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April 30, 2003

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By Authority of the
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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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☐ *Additional inventors are being named on the ____ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (280 characters max)

TRANSPEDICULAR INTERVERTEBRAL BODY FUSION

Direct all correspondence to: CORRESPONDENCE ADDRESS

☒ Customer Number 23676 →

OR *Type Customer Number here*

23676
PATENT TRADEMARK OFFICE

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* 60
☒ Drawing(s) *Number of Sheets* 9
☐ Application Data Sheet. See 37 CFR 1.76
☐ CD(s), Number
☐ Other (specify)

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT *(check one)*

☒ Applicant claims small entity status. See 37 CFR 1.27.
☐ A check or money order is enclosed to cover the filing fees
☒ The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number 19-2090
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.
☒ No.
☐ Yes, the name of the U S. Government agency and the Government contract number are ____

Respectfully submitted,

Date 11/08/02

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REGISTRATION NO. (if appropriate) 38,134

Docket Number: 14307

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USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

P19SMALL/REV05

PATENT 14307

TRANSPEDICULAR INTERVERTEBRAL BODY FUSION

BACKGROUND

The human vertebral bodies and intervertebral discs are subject to a variety of diseases and conditions that change the spacial relationship between the vertebral bodies and the intervertebral discs, causing pain, disability or both. Many of these diseases and conditions also cause instability of the vertebral column. Among these diseases and conditions are degenerated, herniated, or degenerated and herniated intervertebral discs, disc or vertebral body infections and space occupying lesions. Additionally, the vertebral bodies and intervertebral discs are subject to injuries, including vertebral fractures, and to surgical manipulations, that change the spacial relationship between the vertebral bodies and the intervertebral discs, causing pain, disability or both, and that cause instability of the vertebral column.

Surgical treatment of diseases and conditions affecting the spacial relationship between the vertebral bodies and the intervertebral discs have traditionally involved open fusion procedures by making a lengthy incision through the tissues overlying the spinous processes, thereby directly accessing the vertebrae to mechanically fuse two adjacent vertebrae. These procedures result in considerable post-operative pain and a significant incidence of post-operative morbidity, including infection. Further, traditional procedures do not allow the surgeon to directly access the intervertebral space to restore the more normal three-dimensional configuration of the space.

Therefore, there is a need for a new method for treating diseases and conditions that changes the spacial relationship between two vertebral bodies and the intervertebral disc between the two vertebral bodies, or that cause instability of the vertebral column, or both, that is associated with less post-operative pain and a lower incidence of post-operative morbidity. Further, there is a need for a new method for treating diseases and conditions that change the spacial relationship between the vertebral bodies and the intervertebral discs, or that

cause instability of the vertebral column, or both, that allows the surgeon to directly access the intervertebral space to mechanically fuse two adjacent vertebrae.

FIGURES

These and other features, aspects and advantages of the present invention will become better understood from the following description, appended claims, and accompanying figures where:

Figure 1 is a partial cutaway, lateral perspective view of a curved bone drill according to the present invention;

Figure 2 is a partial, lateral perspective view of the drilling cable portion of the curved bone drill of the present invention to be used in a non-over-the-wire technique;

Figure 3 is a partial, cutaway, lateral perspective view of the drilling cable portion of the curved bone drill of the present invention to be used in over-the-wire technique;

Figure 4 is a partial, lateral perspective view of a drilling tip of the curved bone drill of the present invention;

Figure 5 is a lateral perspective view of a guiding tip of the curved bone drill of the present invention;

Figure 6 is a partial, axial cutaway, lateral perspective view of a guiding tip of the curved bone drill of the present invention;

Figure 7 is a partial, cutaway, lateral perspective view of the curved bone drill of the present invention showing the relationship between the drilling shaft, and the drilling cable shown in Figure 2;

Figure 8 is a partial, lateral perspective view of a guiding tube of the curved bone drill of the present invention;

Figure 9 is a partial, lateral perspective view of the lining tube of the curved bone drill of the present invention;

Figure 10 is a lateral perspective view of a retaining tube for incorporation into the curved bone drill of the present invention.

Figure 11 is a lateral perspective view of a deformable band according to the present invention; and

Figure 20 through Figure 28 are partial, cutaway, lateral perspective views illustrating some aspects of the method for treating diseases and conditions that change the spacial relationship between two vertebral bodies and the intervertebral disc, or that cause instability of the vertebral column, or both, according to the present invention.

DESCRIPTION

In one embodiment of the present invention, there is provided a method for treating diseases and conditions that change the spacial relationship between the vertebral bodies and the intervertebral discs, or that cause instability of the vertebral column, or both, that is associated with less post-operative pain and a lower incidence of post-operative morbidity than traditional surgical treatments. In another embodiment, there is provided a method for treating diseases and conditions that change the spacial relationship between the vertebral bodies and the intervertebral discs, or that cause instability of the vertebral column, or both, that allows the surgeon to directly access the intervertebral space to restore a more normal three-dimensional configuration of the space, with or without additionally fusing two adjacent vertebrae.

In another embodiment of the present invention, there is provided a plurality of devices that can be used with the methods of the present invention for treating diseases and conditions that change the spacial relationship between the vertebral bodies and the intervertebral discs, or that cause instability of the vertebral column, or both, or for treating diseases and conditions that change the spacial relationship between the vertebral bodies and the intervertebral discs, or that cause instability of the vertebral column, or both, that allows the surgeon to directly access the intervertebral space to restore a more normal three-dimensional configuration of the space, with or without additionally fusing two adjacent vertebrae. The devices and method of the present invention will now be disclosed in detail.

As used in this disclosure, the term "intervertebral disc" comprises both a normal intact intervertebral disc, as well as a partial, diseased, injured or damaged intervertebral disc.

In another embodiment, the present invention is a curved bone drill. Referring now to Figure 1, there is shown a partial cutaway, lateral perspective view of a curved bone drill according to the present invention. As can be seen, the curved bone drill comprises a drilling cable covered proximally by a drilling shaft, both partially surrounded by a guiding tube. The drilling cable ends distally with a drilling tip, and preferably a guiding tip just proximal to the drilling tip. In a preferred embodiment, the curved bone drill further comprises a retaining tube partially surrounding the guiding tube. Each of these parts will now be disclosed in more detail.

The curved bone drill of the present invention can be used in either an over-the-wire technique or in a non-over-the-wire technique. Referring now to Figure 2, there is shown a partial, lateral perspective view of the drilling cable portion of the curved bone drill of the present invention to be used in a non-over-the-wire technique. As can be seen in Figure 1 and figure 2, the drilling cable comprises twisted wire, such as stainless steel wire, with the ends soldered to prevent unraveling. In a preferred embodiment, the ends are also tapered. The dimensions of the wire will vary with the intended use as will be understood by those with skill in the art with reference to this disclosure. By example only, in a preferred embodiment, the wire is in a 7x19 configuration having a total length when twisted of between about 25 cm and 30 cm, and having an outer diameter of between about 0.9 mm and 1.1 mm. Preferably, the wire is wound counterclockwise.

Referring now to Figure 3, there is shown a partial, cutaway, lateral perspective view of the drilling cable portion of the curved bone drill of the present invention to be used in an over-the-wire technique. As can be seen, the drilling cable comprises an inner layer of twisted wire, such as stainless steel wire, with the ends soldered to prevent unraveling, and having a central channel for passing a guidewire through the inner layer. The drilling cable further comprises an outer layer of one or more than one layer of braided wire. In a preferred

embodiment, the ends of the inner layer of wire are also tapered. The dimensions of the wire used in the inner layer will vary with the intended use as will be understood by those with skill in the art with reference to this disclosure. By example only, in a preferred embodiment, the wire used for the inner layer has a diameter of between about 0.2 mm and 0.3 mm. The total length of the inner layer of wire when twisted is between about 25 cm and 30 cm. The inner layer has an inner diameter of between about 0.6 mm and 0.9 mm, and an outer diameter of between about 1 mm and 1.2 mm. Preferably, the wire is wound counterclockwise.

The outer layer comprises braided wire in either one layer or a plurality of layers. In a preferred embodiment, the braided wire is closely braided, that is, packed, to allow the curved bone drill to function at high torque and with great flexibility. In a preferred embodiment, the outer layer is either triple or quadruple braided. The dimensions of the wire used in the outer layer will vary with the intended use as will be understood by those with skill in the art with reference to this disclosure. By example only, in a preferred embodiment, the wire used for the outer layer has a diameter of between about 0.035 mm and 0.04 mm. The outer layer has an outer diameter of between about 1.2 mm and 1.5 mm, depending on the number of braided layers and the thickness of the wire.

Referring now to Figure 4, there is shown a partial, lateral perspective view of a drilling tip of the curved bone drill of the present invention. As can be seen in Figure 1 and Figure 4, the drilling tip comprises a hardened burr and a shaft, such as available from (Artco). The shaft is cut to an appropriate size by grinding down the proximal end. The dimensions of the drilling tip will vary with the intended use as will be understood by those with skill in the art with reference to this disclosure. By example only, in a preferred embodiment, the burr is between about 2.5 mm and 3 mm in axial length, and the shaft is between about 2.5 mm and 4 mm in length. In a particularly preferred embodiment, the drilling tip has an axial channel to allow the passage of a guidewire. In one embodiment, the channel has a diameter of between about 0.5 mm and 1 mm.

In a preferred embodiment, the curved bone drill further comprises a guiding tip. Referring now to Figure 5 and Figure 6, there are shown a lateral perspective view and a partial, axial cutaway, lateral perspective view, respectively, of a guiding tip used in the curved bone drill of the present invention. As can be seen in Figure 1, Figure 5 and Figure 6, the guiding tip comprises a proximal tubular section and a distal flared section. The guiding tip comprises a hard, biocompatible material, such as hardened stainless steel. The dimensions of the guiding tip will vary with the intended use as will be understood by those with skill in the art with reference to this disclosure. By example only, in a preferred embodiment, the proximal section is between about 3.5 mm and 4 mm in axial length, and the distal section is between about 2.4 mm and 2.6 mm in axial length. The flared portion of the distal section has a maximal sagittal length of between about 2.5 mm and 2.7 mm. In a particularly preferred embodiment, the guiding tip has an axial channel, as shown, to allow the passage of a guidewire. In one embodiment, the channel has a diameter of between about 0.5 mm and 1.5 mm.

The curved bone drill of the present invention further comprises a drilling shaft partially covering the drilling cable proximally. Referring now to Figure 7, there is shown a partial, cutaway, lateral perspective view of the curved bone drill of the present invention showing the relationship between the drilling shaft and drilling cable. As can be seen in Figure 1 and Figure 7, the drilling shaft comprises a hollow, tubular structure configured to fix tightly over the drilling cable. The ends of the drilling shaft are soldered to the drilling cable. In a preferred embodiment, the drilling shaft comprises stainless steel. The dimensions of the drilling shaft will vary with the dimensions of the drilling cable as will be understood by those with skill in the art with reference to this disclosure. By example only, in a preferred embodiment, the outer diameter of the drilling shaft is between about 0.05 mm and 0.15 larger than the outer diameter of the drilling cable. In a preferred embodiment, the inner diameter of the drilling cable is about 1 mm and the outer diameter is about 1.25 mm. The axial length of the drilling cable is between about 8 cm and 8.5 cm.

The curved bone drill of the present invention further comprises a guiding tube partially covering the drilling cable proximally. Referring now to Figure 8, there is shown a partial, lateral perspective view of the guiding tube. As can be seen in Figure 1 and Figure 8, the guiding tube comprises a control portion and a directing portion. The control portion comprises a handle configured to be grasped by an operator allowing the operator to manipulate the curved bone drill in space. In a preferred embodiment, the control portion comprises a direction indicator, such as the extension shown in Figure 8, allowing the operator to ascertain the orientation of the direction portion of the advancing curved bone drill. In another preferred embodiment, the control portion comprises a luer lock at the proximal end.

The directing portion comprises a hollow tubular structure passing into the control portion at the distal end of the control portion. The directing portion has a straight proximal segment, an intermediate section and a straight distal section. In a preferred embodiment, the guiding tube comprises a biocompatible, shaped metal alloy, such as nitinol, that has been processed to return to a shape where the intermediate section has a radius of curvature sufficient to cause the central axis of the straight distal section to orient at an approximately 90° angle from the central axis of the straight proximal section after distortion.

The dimensions of the guiding tube are determined by the intended application of the curved bone drill. By way of example only, the guide tube has the following dimensions. In a preferred embodiment, the outer diameter of the guiding tube is less than about 2.8 mm. In a particularly preferred embodiment, the inner diameter of the guiding tube is greater than about 1.6 mm. In a preferred embodiment, length of the guiding tube is at least about 200 and 250 mm. In a preferred embodiment, the straight proximal section is between about 150 mm and 200 mm. In a preferred embodiment, the intermediate section is between about 40 mm and 60 mm. In a preferred embodiment, the straight distal section is between about 2 mm and 4 mm. In a preferred embodiment, the radius of curvature of the intermediate section, without distortion, is between about 10 mm and 40 mm. In a particularly preferred embodiment, the radius of curvature of the intermediate section, without distortion, is about 25 mm.

The curved bone drill of the present invention further comprises a lining tube between the guiding tube, and the drilling cable and drilling shaft. Referring now to Figure 9, there is shown a partial, lateral perspective view of the lining tube. As can be seen, the lining tube is a lightweight, hollow tubular structure with a flared proximal end that mates with the proximal end of the directing portion to prevent the lining tube from extending too far distally. In a preferred embodiment, the lining tube comprises Teflon®. The dimensions of the lining tube are determined by the intended application of the curved bone drill. By way of example only, the lining tube has the following dimensions. In a preferred embodiment, the outer diameter of the lining tube is between about 0.075 mm and 0.125 mm less than the inner diameter of the guiding tube. The inner diameter of the lining tube is slightly larger than the outer diameter of the drilling cable. The lining tube is between about 25 mm and 40 mm shorter than the guiding tube.

In a preferred embodiment, the curved bone drill of the present invention further comprises a retaining tube. Referring now to Figure 10, there is shown a lateral perspective view of a retaining tube for incorporation into the curved bone drill of the present invention. As can be seen in Figure 1 and Figure 10, the retaining tube comprises a control portion and a directing portion. The control portion comprises a handle configured to be grasped by an operator allowing the operator to advance the retaining tube into the tissues overlying the vertebral column of a patient, and into a vertebral body through a previously made channel. The control portion further allows the operator to withdraw the retaining tube from the tissues overlying the vertebral column of a patient, and from the vertebral body through a previously made channel. In a preferred embodiment, the control portion further comprises elevated guiding supports attached to the direction portion that, when used with corresponding depressions in an overlying transpedicle working sheath, limit rotation of the retaining tube circumferentially with respect to the overlying transpedicle working sheath.

The directing portion comprises a hollow tubular structure extending proximally through the control portion and has a beveled distal end. The directing portion serves to direct

a curved bone drill through the proximal portion of the directing portion and out of the distal beveled end of the directing portion assisting in causing the long axis of the curved bone drill to make an approximately 90° angle with the long axis of the directing portion. In a preferred embodiment, the proximal end of the directing portion comprises a luer lock. In a preferred embodiment, the control portion comprises a direction indicator, such as a tapered extension, as shown, aligned with the beveled distal end of the directing portion and allowing an operator to determine the orientation of the beveled distal end of the directing portion. In another preferred embodiment, the retaining tube comprises a biocompatible, non-flexible material, such as stainless steel. In another preferred embodiment, the beveled end makes an angle of between about 20° and 25° with the long axis of the direction portion. In another preferred embodiment, the outer diameter of the directing portion is between about 3.5mm and 5 mm, and the inner diameter is between about 3 mm and about 4.5 mm. In another preferred embodiment, the directing portion is between about 10 and about 15 cm.

In another embodiment, the present invention is a deformable band for containing bone matrix material within a chamber formed within an intervertebral disc space. Referring now to Figure 11, there is shown a lateral perspective view of the band according to the present invention. As can be seen, the band comprises a thin, biocompatible, deformable band having shape memory to open into a semicircular or circular shape. In a preferred embodiment, the band comprises shaped metal alloy, such as nitinol, that has been processed to return to a shape approximating the boundaries of the empty space within the intervertebral disc space created during the method of the present invention. In a particularly preferred embodiment, the band is coated with a biocompatible sealant, such as hydrogel. The dimensions of the band will vary with the intended use as will be understood by those with skill in the art with reference to this disclosure. By example only, in a preferred embodiment, the band expands upon deployment to approximately 1 cm in height and 2 cm in diameter.

In another embodiment, the present invention is an enucleation device as disclosed in this disclosure.

The present invention further comprises a method for treating diseases and conditions that change the spacial relationship between the vertebral bodies and the intervertebral discs, or that cause instability of the vertebral column, or both, and a method that allows the surgeon to directly access the intervertebral space to directly restore a more normal three-dimensional configuration of the space, with or without additionally fusing two adjacent vertebrae. Referring now to Figure 20 through Figure 28, there are shown partial, cutaway, lateral perspective views illustrating some aspects of the method as performed on a first vertebral body 100 of a first vertebrae 102, a second vertebral body 104 of a second vertebrae 106 and an intervertebral disc 108, between the first vertebral body 100 and second vertebral body 104.

The method comprises, first, selecting a patient who is suitable for undergoing the method. A suitable patient has one or more than one change in the spacial relationship between a first vertebral body of first vertebrae, a second vertebral body of a second vertebrae adjacent the first vertebral body, and an intervertebral disc between the first vertebral body and the second vertebral body, where the change in the spacial relationship is symptomatic, such as causing pain, numbness, or loss of function, or where the change in the spacial relationship is causing real or potential instability, or a combination of the preceding, necessitating a restoration of a more normal configuration of the spacial relationship between the first vertebral body and the second vertebral body, or necessitating fusion of the first vertebrae and the second vertebrae, or necessitating both. However, other diseases and conditions can also be treated by the present methods, as will be understood by those with skill in the art with reference to this disclosure. While the present method is disclosed and shown with respect to the first vertebral body being superior to the second vertebral body, the present method can also be used with respect to a first vertebral body that is inferior to the second vertebral body, as will be understood by those with skill in the art with reference to this disclosure.

Next, transpedicular access to the first vertebral body 100 is obtained percutaneously, as shown in Figure 20. In a preferred embodiment, the transpedicular access is obtained by inserting a suitable gauge bone biopsy needle 110, such as an 11-gauge bone biopsy needle,

through one pedicle 112 of the first vertebrae under suitable guidance, such as fluoroscopic guidance. In a particularly preferred embodiment, transpedicular access is obtained bilaterally. Then, a suitable gauge guidewire, such as a 1 mm diameter guidewire, is inserted into the first vertebral body through the biopsy needle, as shown in Figure 20, and the biopsy needle is removed leaving the inserted guidewire.

Next, a suitable straight bone drill is inserted over the guidewire, as shown in Figure 21, and the straight bone drill is activated under guidance, thereby enlarging the channel created by the biopsy needle and guidewire to approximately 5 mm in diameter and extending into approximately the posterior third of the first vertebral body. In one embodiment, a straight bone drill sheath, not shown, such as a 0.25 mm thick, plastic tube having an outer diameter of 5 mm is inserted over the guidewire through the connective tissues and musculature overlying the first vertebrae before inserting the straight bone drill, and the straight bone drill is inserted over the guidewire but within the straight bone drill sheath. In this embodiment, the straight bone drill sheath protects the connective tissues and musculature overlying the first vertebrae from contact with the straight bone drill.

Next, the straight bone drill sheath is removed and, as can be seen in Figure 22, replaced with a transpedicle working sheath that is inserted over the straight bone drill into the space created by the straight bone drill. The straight bone drill is removed and a retaining tube is advanced through the transpedicle working sheath until the distal tip of the retaining tube exits the distal end of the transpedicle working sheath. Then, a curved bone drill is introduced through the entire length of the retaining tube. In a preferred embodiment, the retaining tube is a device according to the present invention. In another preferred embodiment, the curved bone drill is a device according to the present invention. As shown in Figure 22, the curved bone drill is advanced through the proximal portion of the retaining tube and out of the distal beveled end of the retaining tube causing the long axis of the curved bone drill to make an approximately 90° angle with the long axis of the retaining tube. The curved bone drill is

activated, creating a channel through the first vertebral body and into the intervertebral disc space in a superior to inferior direction.

In a preferred embodiment, a biocompatible wire, between about 0.4 mm and 0.7 mm in diameter, is inserted through the curved bone drill and into the intervertebral disc space to create a support structure. The curved bone drill is removed, leaving the support structure and transpedicle working sheath. In a particularly preferred embodiment, a wire sheath about 1 mm in diameter is advanced through the transpedicle working sheath over the wire to increase the strength of the support structure.

Next, a flexible drill is advanced through the transpedicle working sheath and over the support structure. In one embodiment, the flexible drill is a device according to the present invention. The flexible drill is activated, thereby enlarging the channel created by the curved bone drill into the intervertebral disc space to between about 4 mm and 5 mm in diameter. The flexible drill and transpedicle working sheath are then withdrawn, leaving the support structure in place.

Next, a flexible sheath, such as a flexible braided or metal sheath, is advanced over the support structure through the enlarged channel created by the flexible drill. The support structure is removed. As shown in Figure 23, an enucleation device is advanced through the flexible sheath until the distal end of the enucleation device is within the intervertebral disc space. In one embodiment, the enucleation device is a device according to the present invention. The enucleation device is then activated, as shown in Figure 24, under suitable guidance, such as fluoroscopic guidance, removing approximately a section of intervertebral disc material and one or both endplates comprising a 2 cm section in sagittal cross-section, preferably leaving cortical bone exposed on either the superior aspect of the intervertebral disc space, the inferior aspect of the intervertebral disc space, or preferably both the superior aspect and the inferior aspect of the intervertebral disc space. However, the annulus fibrosis is preferably preserved circumferentially. Then, the enucleation device is removed and the

debris is removed from the intervertebral disc space using suction, by flushing with a suitable solution such as saline or by a combination of suction and flushing.

Next, as shown in Figure 25, a thin, biocompatible, deformable band is introduced into the empty space created by the enucleation device and deployed. In a preferred embodiment, the band is a device according to the present invention. In another preferred embodiment, introduction and deployment of the deformable band is accomplished by tightly coiling the deformable band within a deployment device comprising a flexible tube for containing the coiled band and a central wire having a discharge tip for pushing the coiled band out of the flexible tube and into the empty space created by the enucleation device. Once in the empty space, the deformable band returns to its undeformed shape, creating a lined chamber within the intervertebral disc space. Next, the lined empty chamber is filled with a fusion agent, such as an agent comprising compatible bone matrix (for example, Vitoss™ available from Orthovita, Malvern, PA US), thereby creating a boney fusion between the first vertebral body and the second vertebral body.

In a preferred embodiment, the method further comprises introducing a distraction structure into the chamber, either before filing the chamber with the fusion agent, or after filing the chamber with the fusion agent. Alternately,. the chamber can be partially filled with a fusion agent, the distraction structure introduced and an additional fusion agent can be added to the chamber. The distraction structure serves to distract, that is, to increase axial separation of the first vertebrae from the second vertebrae.

The distraction structure can be any suitable structure, as will be understood by those with skill in the art with reference to this disclosure. In a preferred embodiment, the distraction structure is a distraction structure according to the present invention. Referring now to Figure 26, Figure 27 and Figure 28, there are shown sequential aspects of deployment of a distraction structure.

In a preferred embodiment, the method further comprises performing an additional fusion procedure to join the first vertebrae with the second vertebrae. In one embodiment, as

can be seen in Figure 28, the additional fusion procedure comprises placing pedicle screws into the transpedicular channel left from performing the method of the present invention, and joined by spacing devices. However, any suitable additional fusion procedure can be used, as will be understood by those with skill in the art with reference to this disclosure.

Although the present invention has been discussed in considerable detail with reference to certain preferred embodiments, other embodiments are possible. Therefore, the scope of the appended claims should not be limited to the description of preferred embodiments contained in this disclosure. All references cited herein are incorporated by reference to their entirety.

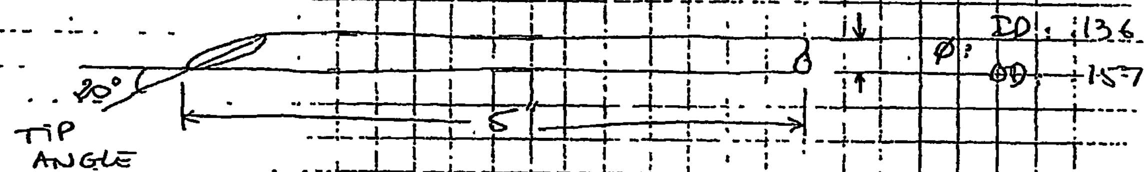
As used herein, the term "comprise" and variations of the term, such as "comprising" "comprises" and "comprise," are not intended to exclude other additives, components, integers or steps.

I. OBJECTIVE: TO PROTOTYPE A DRILLING TOOL USING IN ORTHOPEDIC PROCEDURE

II. MATERIALS:

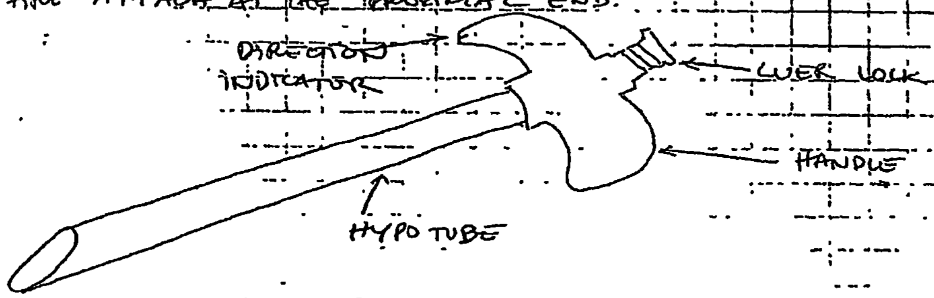
1. RETAINING TUBE: HYPOTUBE, STAINLESS STEEL DIMENSIONS LESS THAN 5MM (.197") OUTSIDE DIAMETER AND AT LEAST 5 IN. LONG.

* INITIAL PROTOTYPE DIMENSIONS:



a). THE DISTAL END IS CUT AT 20°-25° ANGLE FOR THE DRILL EASILY ACCESSED.

b) A LUER LOCK AND A HANDLE WITH DIRECTION INDICATOR ARE ATTACH AT THE PROXIMAL END.



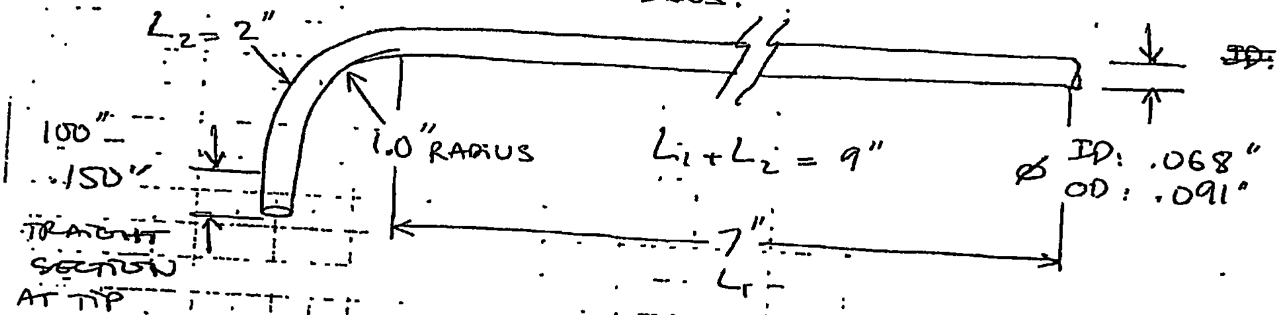
c. THE DIRECTION INDICATOR IS ALIGNED WITH THE OPENING OF THE ANGLE CUT AT THE DISTAL END

PATENT

14307

2. GUIDING TUBE: PRE-SHAPED NITINOL TUBE.
DIMENSIONS: LESS THAN ~~HO~~ 2.8 MM (.110") IN OD AND LARGER THAN 1.6 MM (.063") IN ID, AT LEAST 9" IN WORKING LENGTH, CURVE RADIUS FROM .5" TO 1.5"

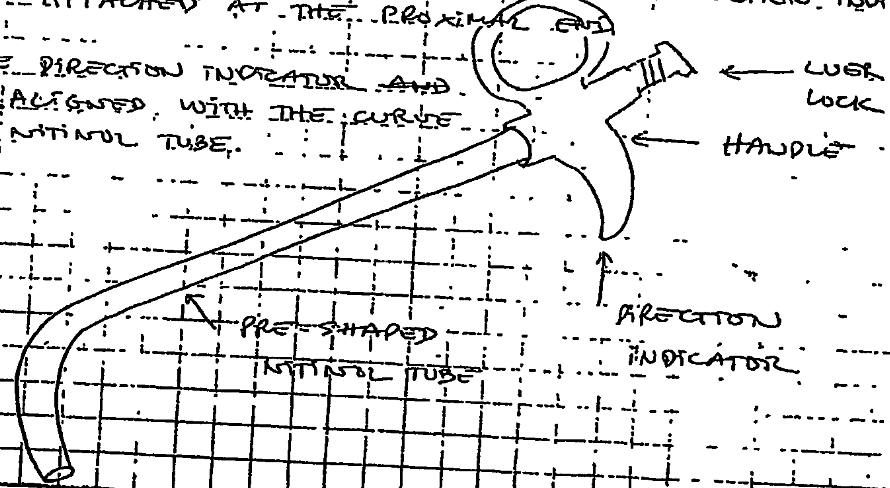
* INITIAL PROTOTYPE DIMENSIONS.



a.) THE DISTAL END IS SQUARE CUT AND PRESHAPED AT A RADIUS OF .5" TO 1.5" (DEPENDING ON APPLICATION AND PROCEDURE)

b) A LUER LOCK AND A HANDLE WITH DIRECTION INDICATOR ARE ATTACHED AT THE PROXIMAL END

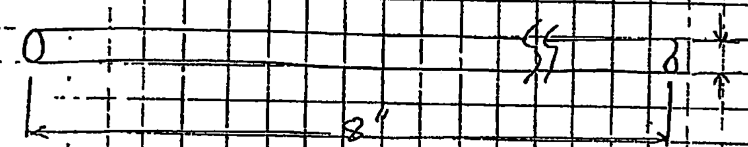
c) THE DIRECTION INDICATOR ~~AND~~ IS ALIGNED WITH THE CURVE OF NITINOL TUBE.



PATENT

3. TEFLON LINER: THIN WALL TEFLON TUBING.
DIMENSIONS: OD IS SMALLER THAN ID OF NITINOL TUBING ABOUT .003" TO .005", AND ID IS ~~AT LEAST~~ LARGER THAN THE OD OF DRIVING CABLE/SHAFT, 1.0" TO 1.5" SHORTER THAN THE LENGTH OF NITINOL TUBING

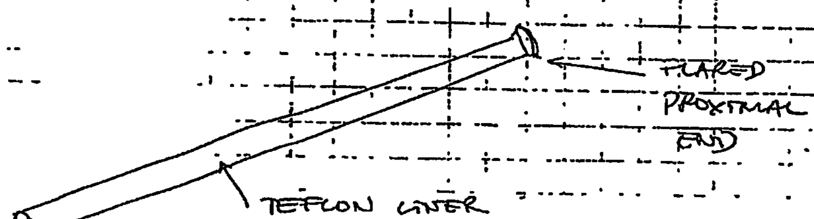
INITIAL PROTOTYPE DIMENSIONS:



TEFLON TUBING #16 LIGHTWEIGHT ID: .053", WALL: .006"
STRETCHED TO .066" OD AND .052" ID (WITH .051" MANDREL AT HIGH TEMPERATURE)

a) THE PROXIMAL END IS FLARED TO RETAIN INSIDE THE LUER LOCK ON THE PROXIMAL END OF NITINOL TUBE

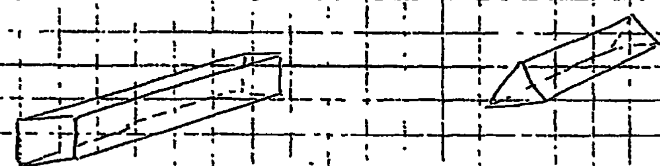
b) THE LENGTH OF TUBING WOULD BE CALCULATED SO THAT IT WOULD NOT EXTEND TOO LONG INTO THE TIP SECTION. IT IS OK TO COVER THE CURVED SECTION.



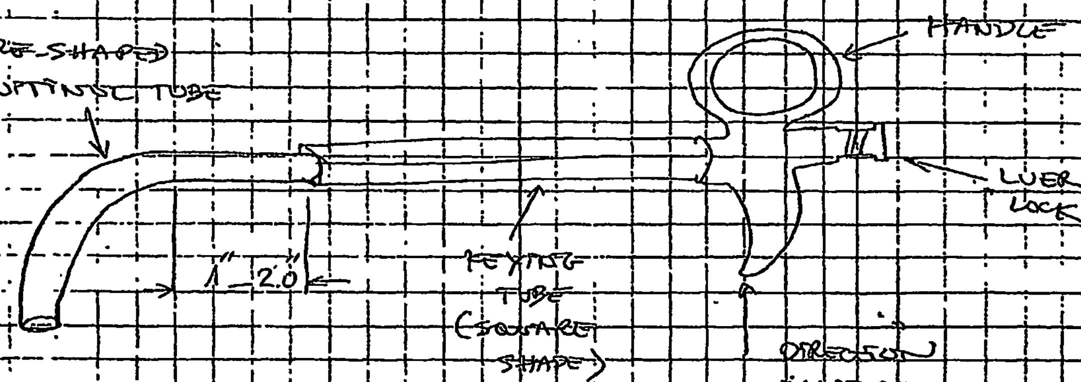
4. KEYING TUBE : PRE-SHAPED STAINLESS STEEL TUBE.
DIMENSIONS: THE ID SHOULD BE SNUG FIT TO THE OD OF NITINOL TUBING, AND THE OD SHOULD BE SMALLER THAN THE ID OF THE RETAINING TUBE, THE LENGTH SHOULD BE 1.0" _ 2.0" SHORTER THAN THE LENGTH L_1 OF THE NITINOL TUBE (GUIDING TUBE

* INITIAL PROTOTYPE DIMENSIONS:
NOT APPLICABLE !

a) THE SHAPE OF THE KEYING TUBE COULD BE SQUARE OR TRIANGLE. THIS TUBE WOULD BE SNUG FIT TO THE OD OF



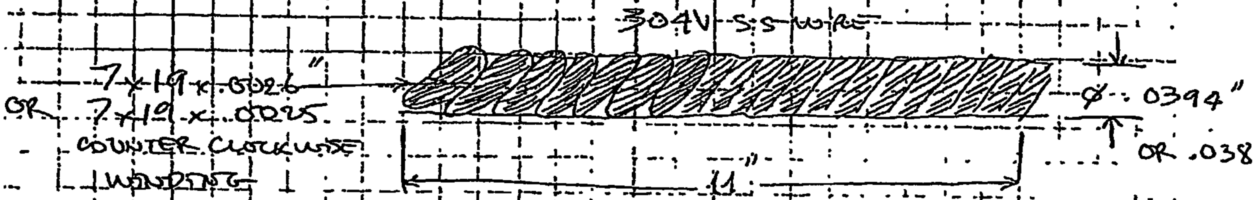
THE GUIDING (NITINOL) ~~TUBING~~ TUBE. IT WOULD BE SLIDE OVER ~~THE~~ AND ATTACHED TO THE GUIDING TUBE AT THE PROXIMAL END



b) THE LENGTH OF KEYING TUBE SHOULD BE 1.0"_2.0" SHORTER THE STRAIGHT SECTION L_1 OF GUIDING (NITINOL TUBE

5. DRILLING CABLE: STAINLESS STEEL TWISTED WIRE.
DIMENSION: 7x19 CONFIGURATION AND FINAL OD IS FROM .038" – .042", COUNTER CLOCKWISE WINDING, 11"L

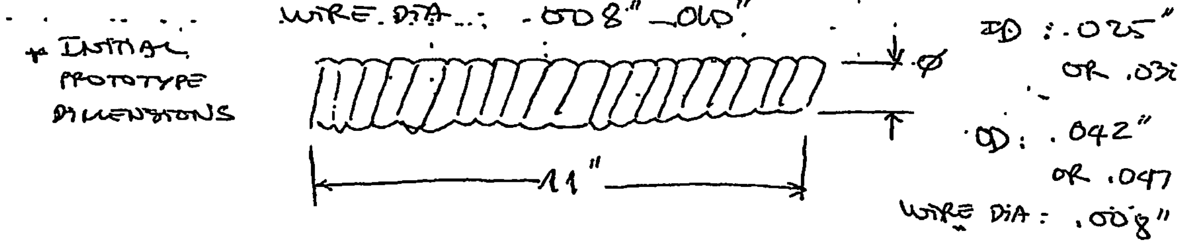
* INITIAL PROTOTYPE DIMENSION



a) THE TWISTED WIRE WOULD BE USED FOR NON-OVER-THE-WIRE DRILLING TECHNIQUE. AND THE ENDS SHOULD BE TAPED OR SOLDERED TO KEEP FROM UNRAVEL.

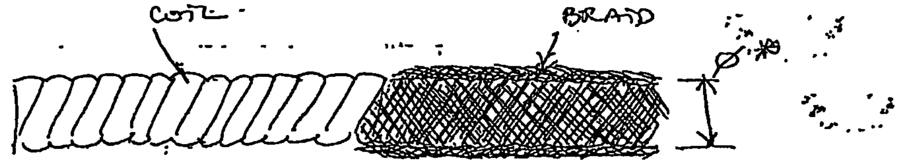
b) THE OVER THE WIRE DRILLING CABLE COULD BE FABRICATED IN THE COMBINATION OF INNER COIL AND OUTER BRAIDED WIRE. THE INNER COIL WOULD BE CLOSELY WOUND AND COUNTER-CLOCKWISE (OR RIGHT HAND) WOUND AT THE DIMENSIONS:

304 S.S. COIL ID: .025" – .035"
OD: .041" – .051"
WIRE DIA: .008" – .010"



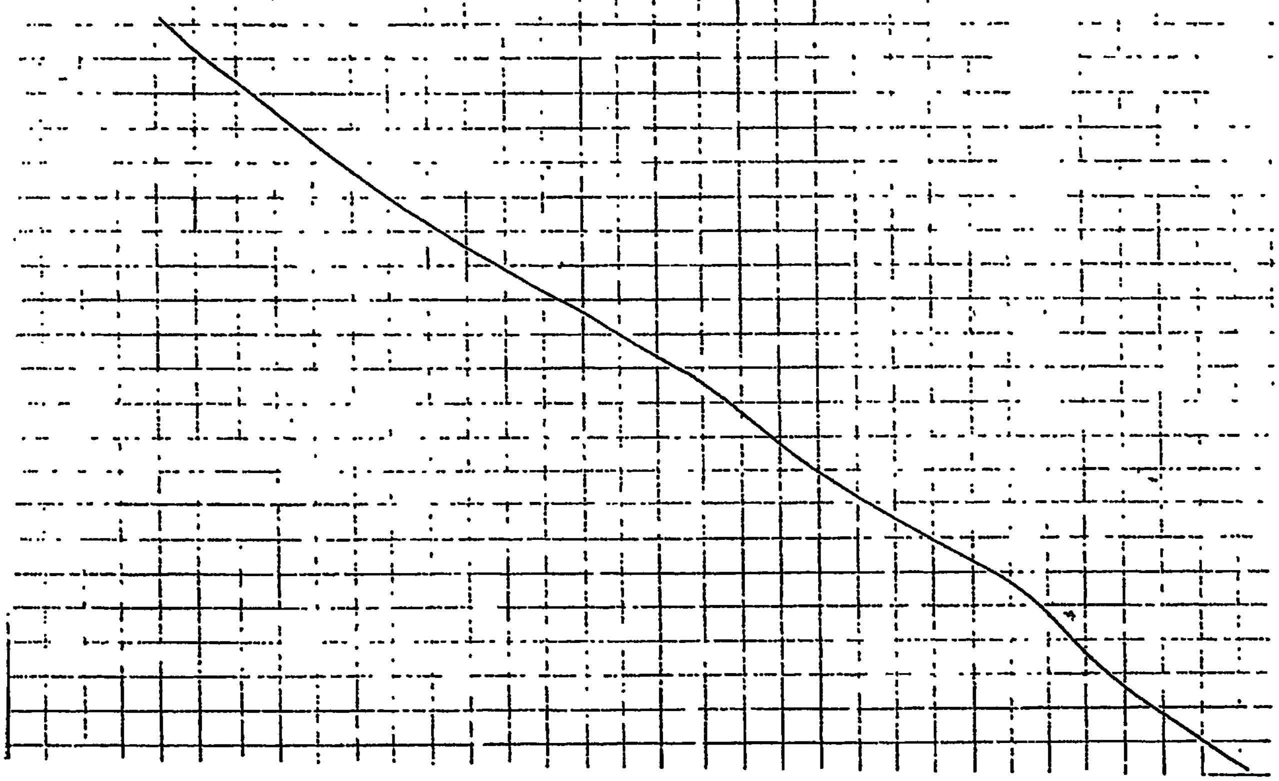
c) BRAIDED WIRE WOULD BE .0015" – .0020" IN DIAMETER AN WOULD BE SINGLE LAYER OR DOUBLE LAYER BRAID. THE BRAID WIRE WOULD BE TRIPLE OR QUAD BRAIDING. THE BRAID SHOULD BE CLOSELY BRAIDED (OR PACKED) TO ACHIVE HIGH TORQUE AND FLEXIBILITY.

* INITIAL PROTOTYPE DIMENSIONS:



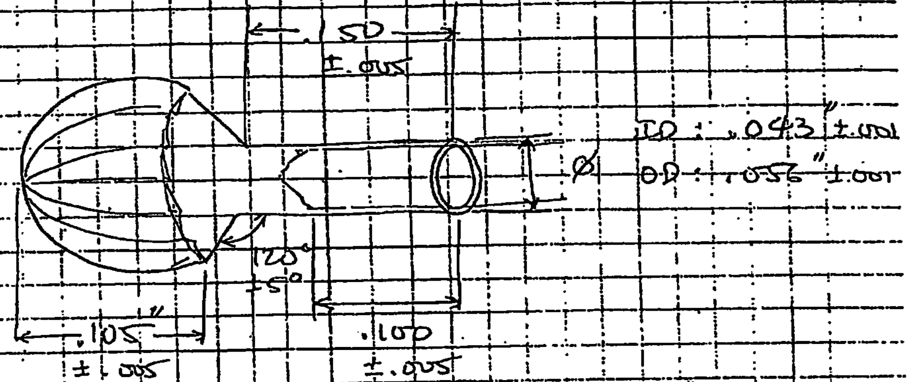
BRAID WIRE DIA: .0015", STAINLESS STEEL - 304 ~~FINAL OD: SINGLE LAYER: .048 - .049 OR.~~

FINAL OD	SINGLE LAYER, SMALL COIL	:	.048 - .049
	SINGLE LAYER, LARGE COIL	:	.053 - .054
	DOUBLE LAYER, SMALL COIL	:	.054 - .055
	DOUBLE LAYER, LARGE COIL	:	.059 - .060



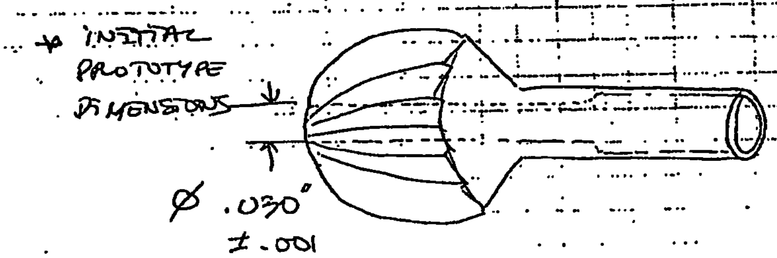
6. DRILLING TIP: HARDENED BURR, .120" - .130" IN DIAMETER, SHORT SHAFT WITH ~~CONDUCT~~ HOLE.

* INITIAL PROTOTYPE DIMENSIONS:



a) THE TIP IS ORDERED FROM VENDOR (ARTCO (626) 358 8466) P/N. SI/033 H, THEN GRIND THE SHAFT DOWN TO DESIRED OD AND ANGLE. FINALLY, EDM THE HOLE TO SIZE AND DEPTH

b) AN OPTION FOR OVER-THE-WIRE DRILLING TIP IS TO MAKE THE HOLE THROUGH ALL THE WAY OUT TO THE END OF TIP WITH DIAMETER OF .025" - .038"

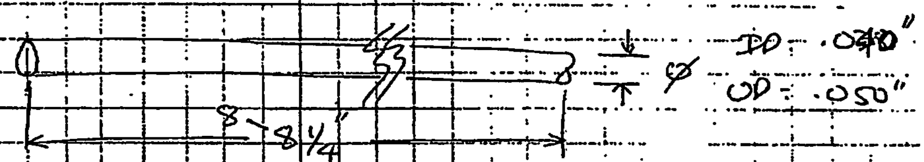


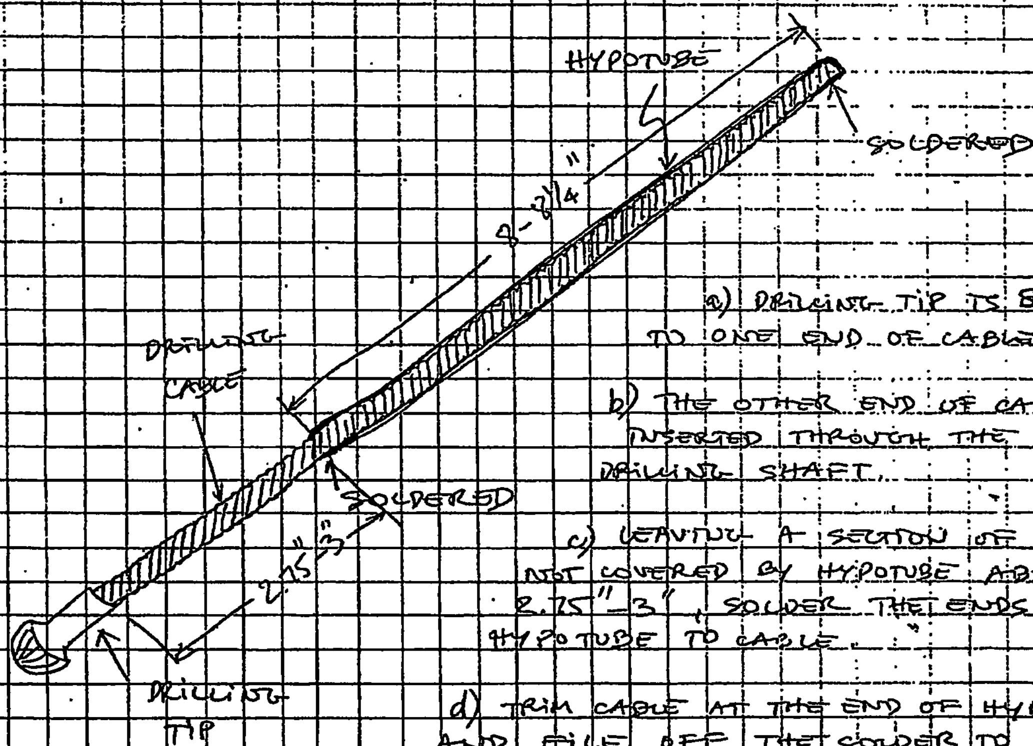
SCANNED, # 6

PATENT

7. DRILLING SHAFT : 304 S.S. HYPOTUBE. OD OF DIMENSION; ID SHOULD BE LARGER THAN THE DRILLING CABLE FROM .002 TO .005", AND THE OD SHOULD BE SMALLER THAN THE ID OF TEFLON LINER TUBING ABOUT .002" - .003", L ≈ 8"-8.

* INITIAL PROTOTYPE DIMENSIONS:





a) DRILLING TIP IS SOLDERE[D] TO ONE END OF CABLE

b) THE OTHER END OF CABLE [IS] INSERTED THROUGH THE HYPOT[UBE] DRILLING SHAFT.

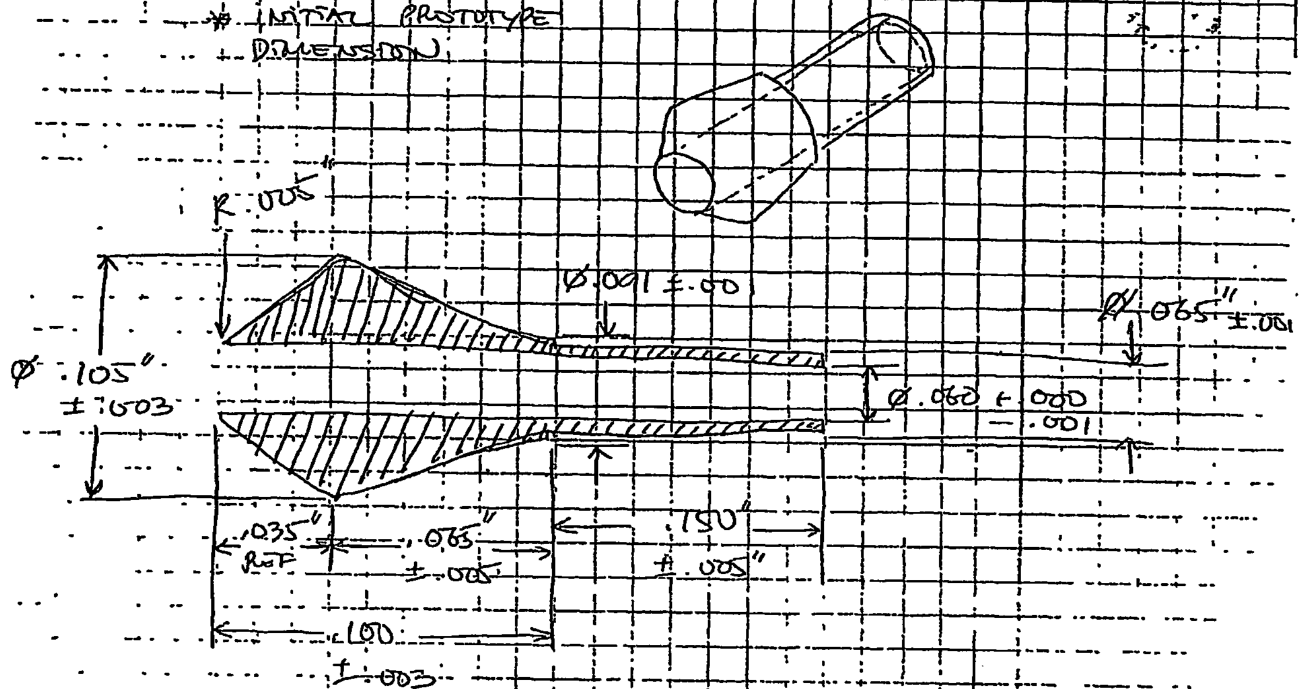
c) LEAVING A SECTION OF CABLE NOT COVERED BY HYPOTUBE ABOUT 2.75" - 3", SOLDER THE ENDS OF HYPOTUBE TO CABLE.

d) TRIM CABLE AT THE END OF HYPOTUBE AND FILE OFF THE SOLDER TO KEEP THE OVERALL OD AT .050"

PATENT 14307

8. GUIDING TIP 440 C STAINLESS STEEL, HARDENED AT 50-55 HRC

* INITIAL PROTOTYPE DIMENSION

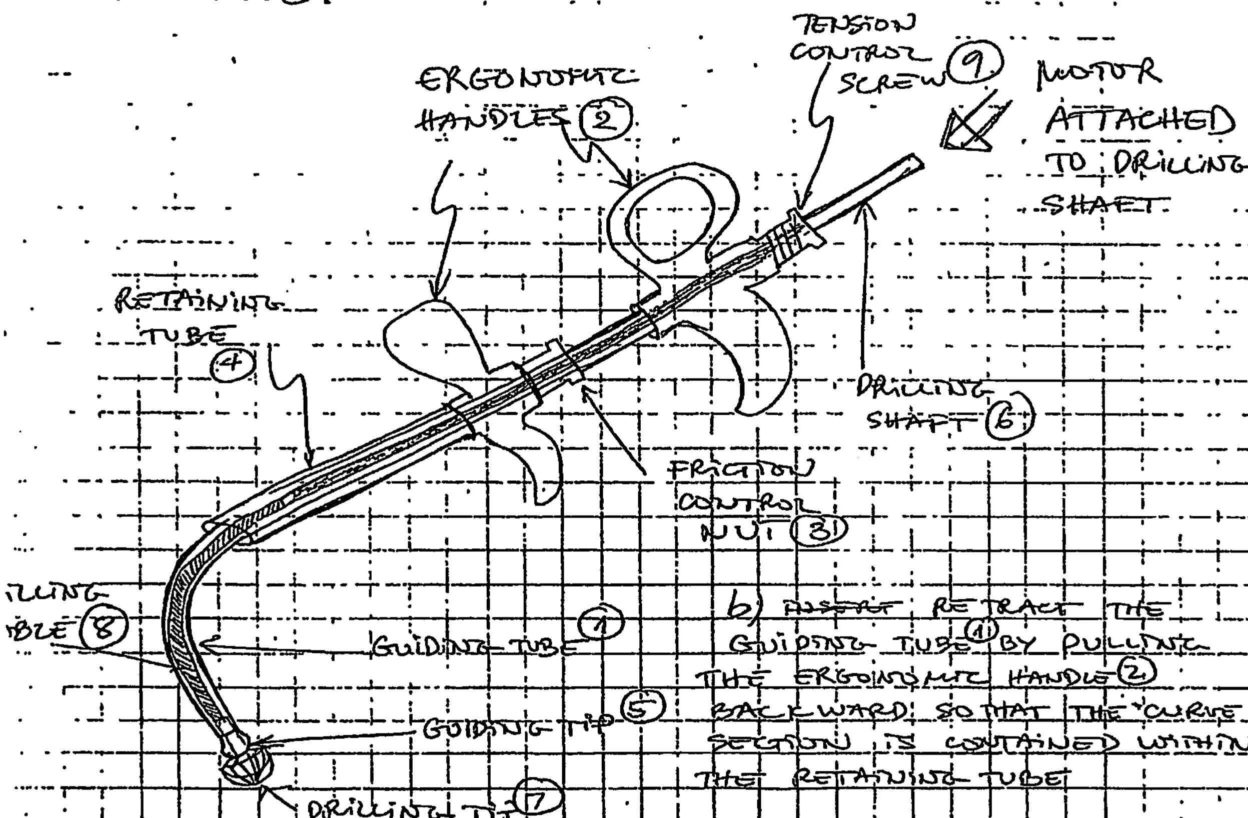


a) PART IS MADE OF 440 C STAINLESS STEEL WITH DIMENSIONS AS SPECIFIED

b) IT WOULD BE HARDEND AT 50-55 HRC
- HARDEN @ 1825 °F FOR 1H, GAS FAN COOL
- TEMPER @ 625 °F FOR 2H.

~~a) DRILLING SHAFT SLIDES OVER A TEFLON TUBING.~~

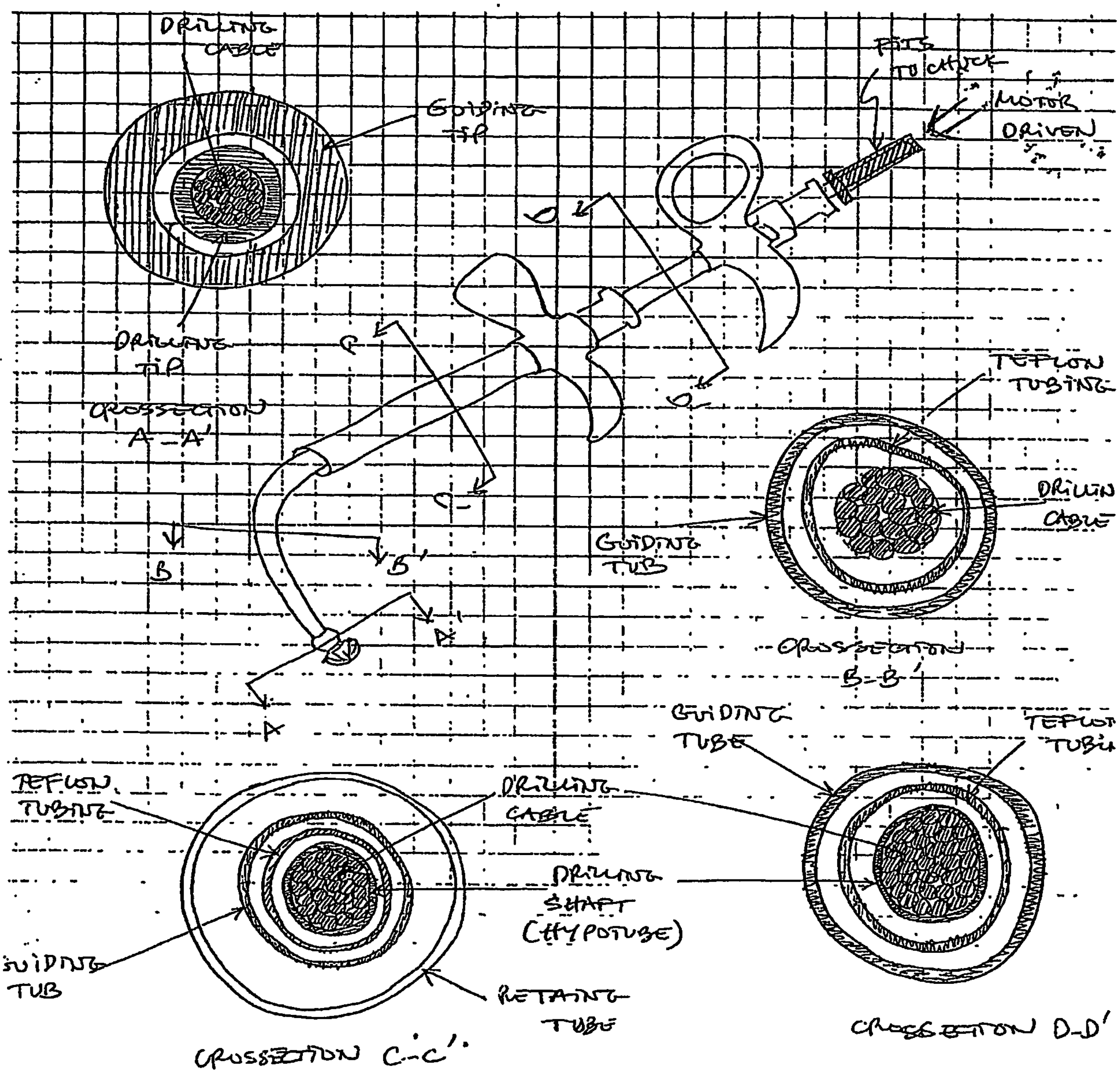
~~b) ART~~ a) INSERT GUIDING TUBE (1) WITH ERGONOMIC HANDLE (2) THROUGH THE FRICTION CONTROL NUT (3) AND THE RETAINING TUBE (4) FROM THE PROXIMAL END. THE GUIDING TIP (5) IS ALREADY PRE-WELDED TO THE GUIDING TUBE (1).



b) ~~INSERT~~ RETRACT THE GUIDING TUBE (1) BY PULLING THE ERGONOMIC HANDLE (2) BACKWARD SO THAT THE CURVE SECTION IS CONTAINED WITHIN THE RETAINING TUBE

c) SLIDE A TEFLON TUBING (NOT SPECIFIED) OVER THE DRILLING SHAFT (6) WITH DRILLING TIP (7) ATTACHED AND DRILLING CABLE (8) ATTACHED. SLIDE THE DRILLING SHAFT (6) THROUGH THE GUIDING TUBE (1) FROM DISTAL END.

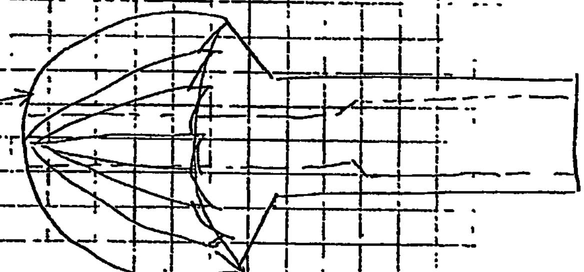
d) ATTACH CHUCK ADAPTOR (NOT SHOWN) TO THE END OF DRILLING SHAFT (6) AND ADJUST TENSION CONTROL SCREW (9) FOR PROPER TENSION.


DRILLING CABLE
GUIDING TIP
FITS TO CHUCK
MOTOR DRIVEN
D
D'
C
C'
DRILLING TIP
CROSSECTION A-A'
TEFLON TUBING
DRILLIN CABLE
GUIDING TUB
B
B'
A'
A
CROSSECTION B-B'
GUIDING TUBE
TEFLON TUBI
TEFLON TUBING
DRILLING CABLE
DRILLING SHAFT (HYPOTUBE)
GUIDING TUB
RETAING TUBE
CROSSECTION C-C'
CROSSECTION D-D'

I OBJECTIVE: TO PROTOTYPE A DRILLING TOOL THAT ULTILIZES THE OVER-THE-WIRE TECHNIQUE.

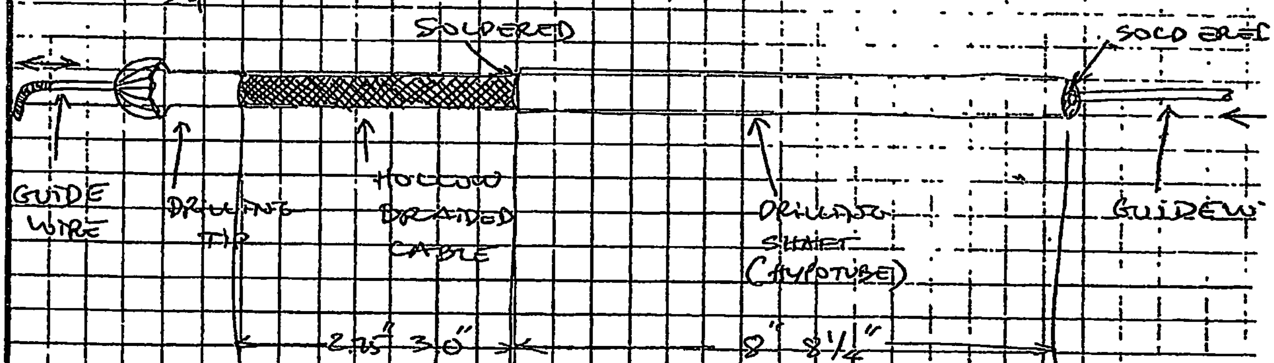
II MATERIAL: THE MATERIAL AND CONCEPT ARE BASICALLY THE SAME AS THE PREVIOUS DRILLING TOOL

1) THE DRILLING TIP WOULD BE THE SAME AS THE DESIGN SPECIFIED ON PAGE # 28 WITH THE HOLE DRILLING THROUGH AT TIP. THE DRILL DIAMETER WOULD BE INCREASED UP TO 5mm



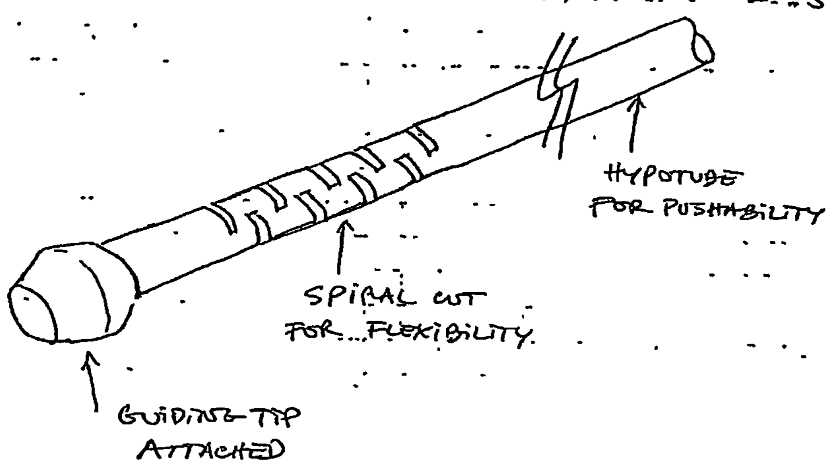
2) DRILLING CABLE WOULD BE USED AND SPECIFIED AS ON PA 26 AND 27. THE CABLE WITH HOLLOW DIAMETER (A COMPRE COIL) WOULD BE SOLDERED TO THE TIP.

3) DRILLING SHAFT WOULD BE PREPARED AS SPECIFIED ON PAG 29



4) GUIDING TIP: WOULD BE THE SAME AS SPECIFIED ON PAGE #30

5) GUIDING TUBE: STAINLESS ~~STEEL~~ TUBE WITH SPIRAL CUT AT THE DISTAL END ABOUT 5-6 CM FOR FLEXIBILITY. THE GUIDING TIP WOULD BE ATTACHED TO THE DISTAL END. THE LENGTH WOULD BE 12" ± .5"



6) TEFLON LINER: THIN WALL TEFLON TUBING.
DIMENSIONS: ~~WOULD BE~~ ID WOULD BE LARGER THAN THE OVERALL OD OF DRILLING CABLE FROM .003" .005". AND THE OD ~~OF~~ WOULD BE SMALLER THAN THE ID OF GUIDING TUBE FROM .005" - .010". THE LENGTH WOULD BE SHORTER THAN THE GUIDING TUBE ABOUT .5" - 1.0".

[redacted]

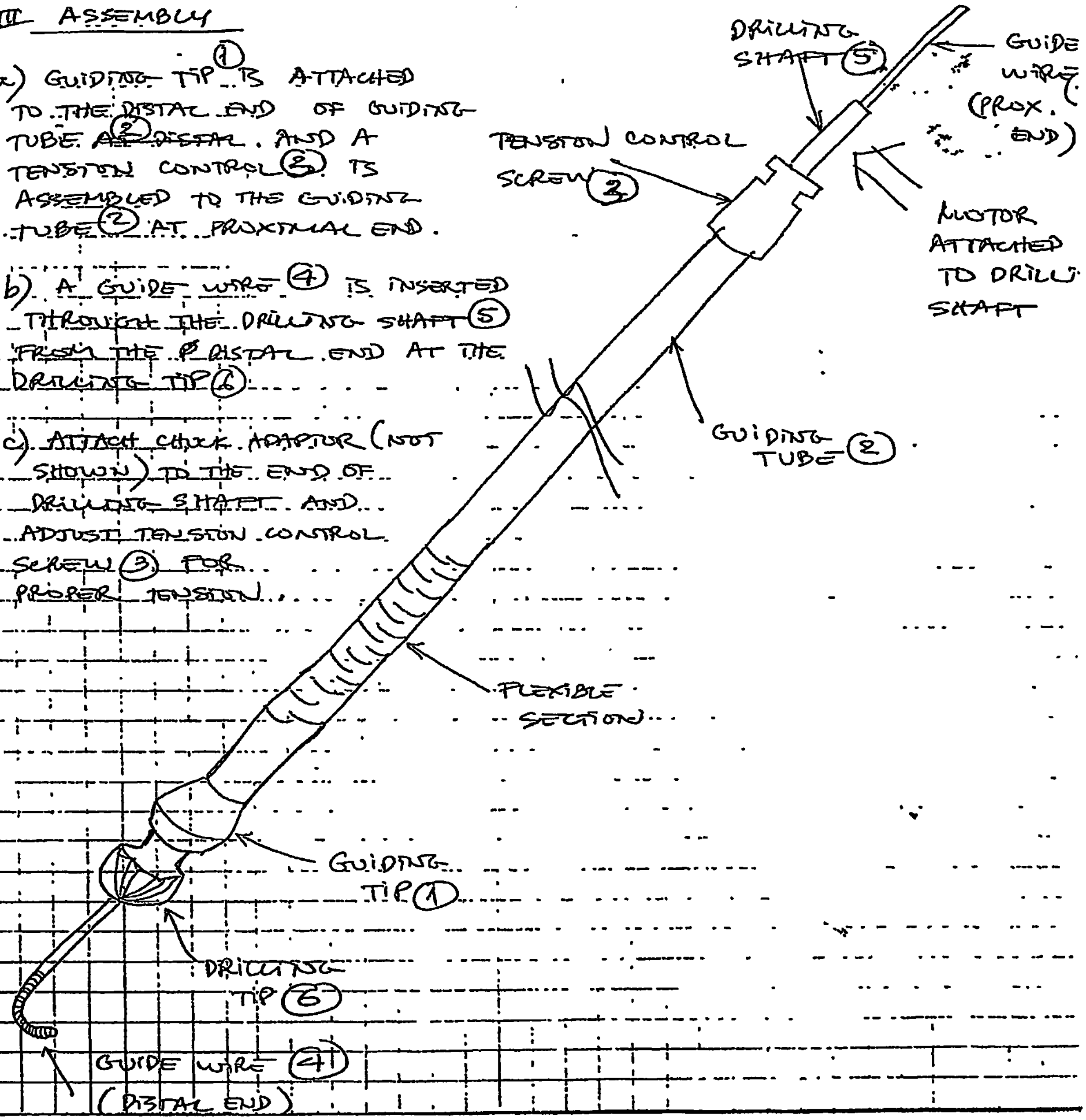
PATENT 14307

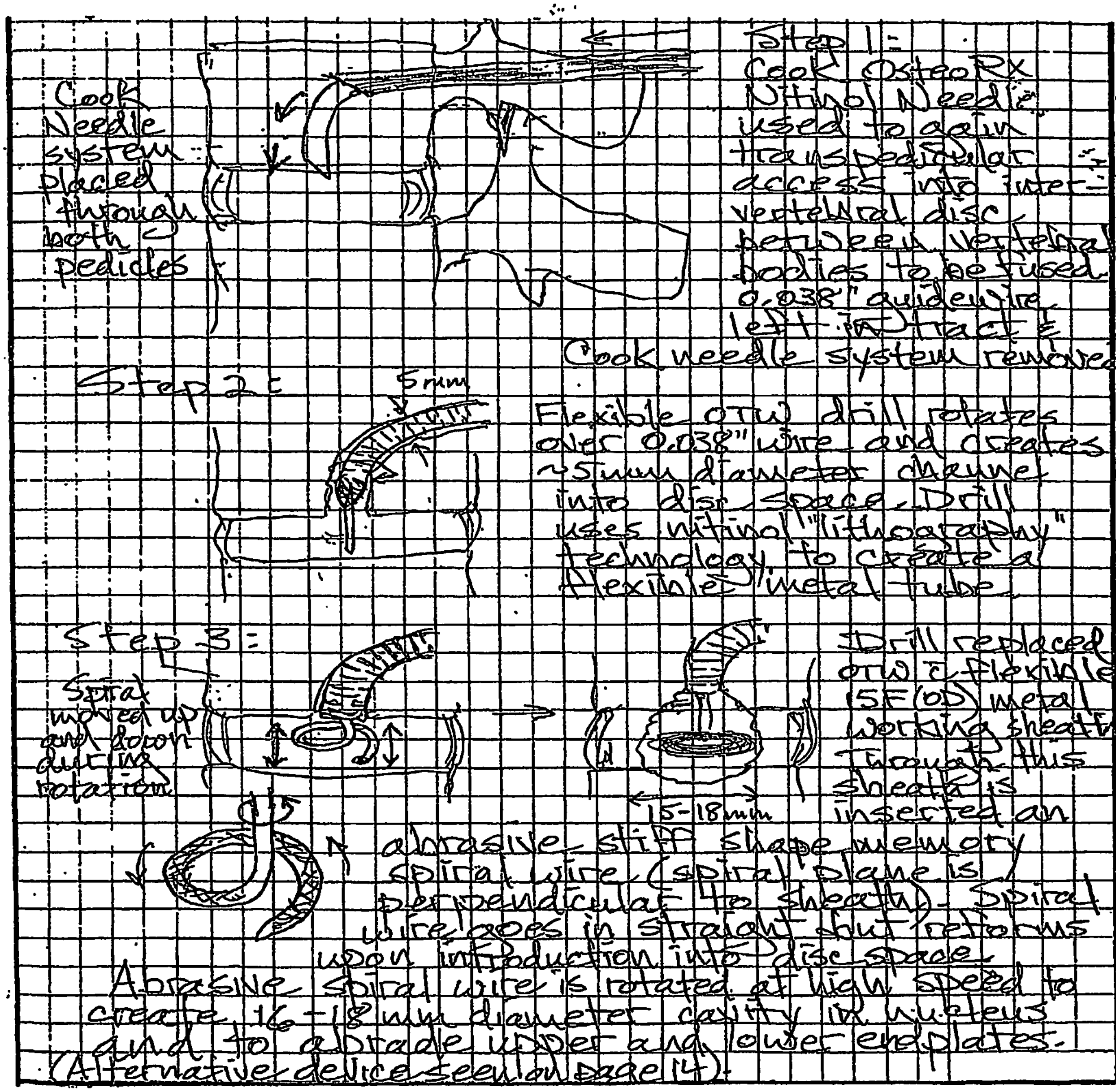
III ASSEMBLY

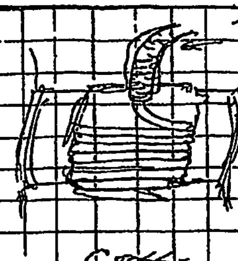
a) GUIDING TIP (1) IS ATTACHED TO THE DISTAL END OF GUIDING TUBE (2) ~~AT DISTAL~~. AND A TENSION CONTROL (3) IS ASSEMBLED TO THE GUIDING TUBE (2) AT PROXIMAL END.

b) A GUIDE WIRE (4) IS INSERTED THROUGH THE DRILLING SHAFT (5) FROM THE ~~Ø~~ DISTAL END AT THE DRILLING TIP (6).

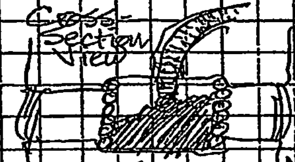
c) ATTACH CHUCK ADAPTOR (NOT SHOWN) TO THE END OF DRILLING SHAFT AND ADJUST TENSION CONTROL SCREW (3) FOR PROPER TENSION.




Step 1:
Cook OsteoRX Nitinol Needle used to gain transpedicular access into intervertebral disc between vertebral bodies to be fused. 0.038" guidewire left in tract & Cook needle system removed.
Cook Needle system placed through both pedicles
Step 2:
5mm
Flexible OTW drill rotates over 0.038" wire and creates ~5mm diameter channel into disc space. Drill uses nitinol "lithography" technology to create a flexible metal tube.
Step 3:
Spiral moved up and down during rotation
15-18mm
Drill replaced OTW c flexible (5F(OD)) metal working sheath. Through this sheath is inserted an abrasive stiff shape memory spiral wire (spiral plane is perpendicular to sheath). Spiral wire goes in straight but reforms upon introduction into disc space.
Abrasive spiral wire is rotated at high speed to create 16-18mm diameter cavity in nucleus and to abrade upper and lower endplates.
(Alternative device seen on page 14).



Next, after the newly-created intervertebral cavity is flushed c̄ saline solution to remove bone & nuclear debris, a shape-memory nitinol "coil" device is introduced into this cavity.

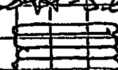


Next, the central well or cavity created by the placement of this "stacked coil" device is filled c̄ bone matrix material mixed c̄ bone marrow + ? BMP to effect bony fusion. This percutaneous cage is placed bilaterally within the disc space.

Once "cage" + bone matrix material is placed within the intervertebral space, the same transosseous tract is used to place pedicle screw into vertebral body.

A number of designs for the cage are possible:

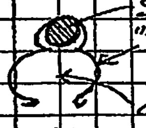
(1) "Flat wire" helix made from nitinol —

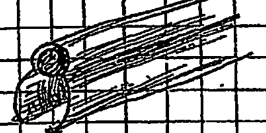


May assist in interlocking of flat layers

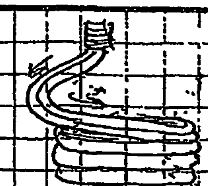
(Sam's, Tom's, & Thabi's idea)

(2) Interlocking nitinol design —



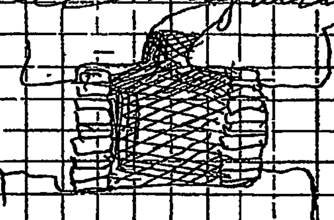


As each helical turn or layer is extruded from the delivery catheter, it "snaps" onto the smaller upper component of the [illegible] sheath immediately below. This is similar to the action of a "zip-lock" bag. Once "zipped" together, the turns of the helix (which together form a cylinder) resist toppling over and separation.

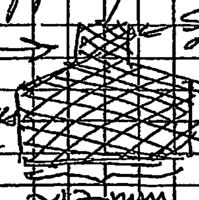


The ends of the flat wire & "zip-lock" helical devices can be sharpened so that they can be embedded in the adjacent endplate or cancellous bone, thus anchoring the device in the intervertebral disc space.

With either of the above designs a central stent-like structure could be expanded in the cavity within the cylinder to help prevent overall device migration and "toppling" of the spiral layers comprising the hollow cylinder.

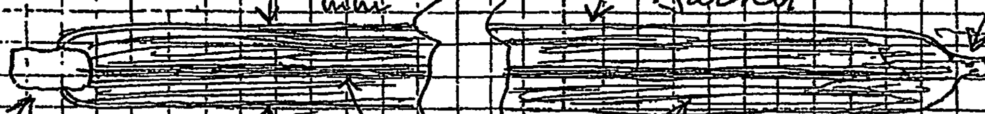


Smaller upper portion of stent anchors stent in transosseous pathway

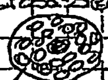


The self-expanding initial stent would be hollow centrally. The spaces between stent struts at the "shoulder" zone would facilitate through-growth of new bone & space is filled c̄ bone matrix material.

(3) Expandible helical balloon design
(See page 46)

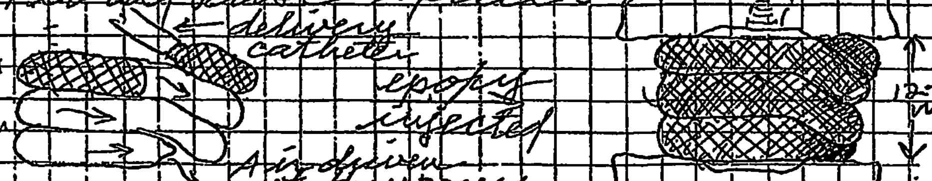


Cross Section

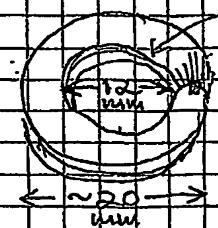


Alternatively, shape can be conferred by inner action of coil:

This design would overcome the dilemma created by the other all-metal designs namely the difficulty in deploying the helical device all the way to the top of the intervertebral disc space. The helical balloon would have a balloon diameter of approx 3 mm during insertion. But once fully inflated with epoxy (thus creating the composite structure) the balloon diameter would expand to 3.5-4.0 mm, effectively raising the inflated cylinder height to fit exactly the height of the intervertebral disc space.

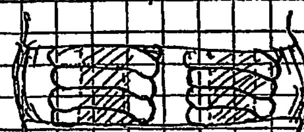


Overhead View:



The central chamber of this hollow cylinder is filled c̄ bone matrix material to create a bony fusion.

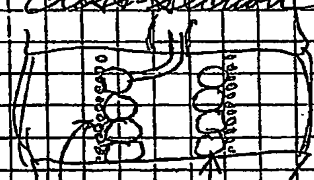
Front View:



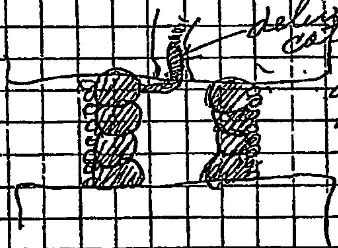
Bilateral fusion cages in place

The expandable balloon cage could be "reinforced" and stabilized in position by means of an outer nitinol self-expanding tubular stent/sleeve and a central "shouldered" dual diameter nitinol stent (see page 65) which anchors the cage to the transosseous vertebral delivery pathway.

Cross-section

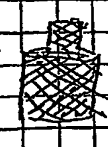


epoxy injected



delivery catheter pusher detached after inflation

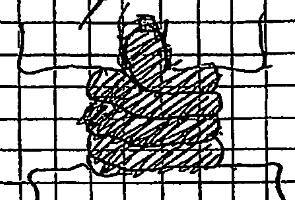
Shouldered Stent deployed



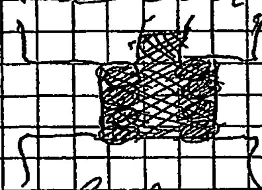
Central anchoring stent

cavity now filled c̄ matrix material

Alternatively, the coil composite cage could be anchored in position by expanding the proximal length of the composite coil within the trans-osseous pathway.

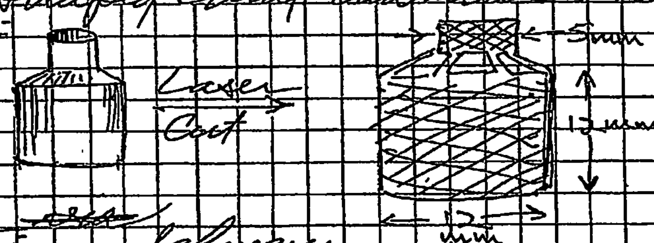


Or, the "shoulderd" stent could first be deployed outside of the composite coil.



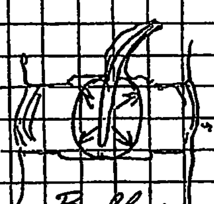
Once the composite coil is inflated c̄ epoxy, it is detached from its delivery catheter (with the proximal self-sealing valve preventing leakage of epoxy.

The "shouldered" stent could be derived from a specially-shaped dual-diameter nitinol metal sleeve.



Self-expanding stent is delivered to created disc space cavity constrained in a delivery catheter

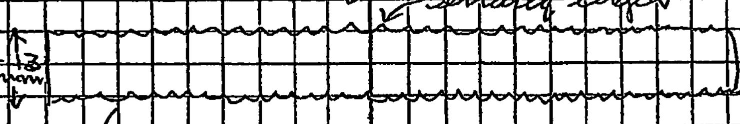
After disc space cavity is created and the endplates are abraded, the disc space height can be increased prior to cage deployment by expansion of a high pressure thick-wall balloon (: tamponade balloon):



Balloon placed bilaterally

Cage is composed of multiple layers of a spiral band inserted like a wound-up "watch spring". Each layer is composed of a thin shape-memory (Nitinol) metallic band having serrated edges and a thickness of ≤ 0.5 mm. When released within the disc space, the band goes from spiral configuration to a hollow cylinder. It is the collective strength of the layers that imparts the overall supportive strength to the final cage. Each complete cage would be expected to support ~180 lbs. of compressive force.

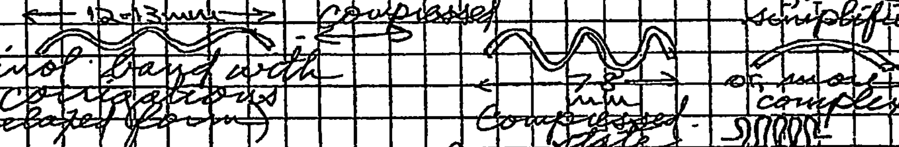
Serrated edges



12-13 mm

cage made from ≤ 1 mm thick Nitinol band

Cross-Section:



← 12-13 mm →

compressed

Nitinol band with corrugations (Relaxed form)

← 7-8 mm → Compressed state

or, more simplified

or, more complex

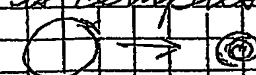
The band is heat annealed into a ring:

← 18-20 mm →

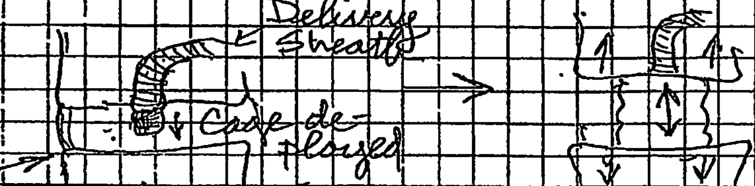
Relaxed State 12-13 mm

The serrated edges help to stabilize the device against the endplates.

For implantation, the ring is compressed down like a watch-spring:



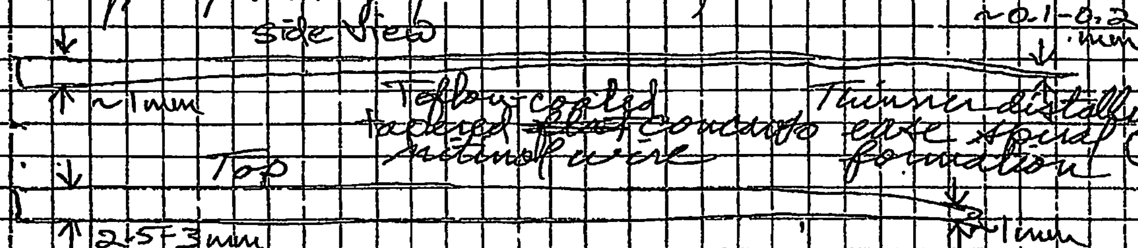
The cooled coiled-up cage is now longitudinally or axially ~~compl~~ compressed to reduce its height for insertion between endplates



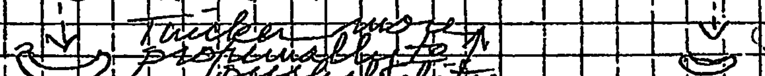
Compressed cage is delivered to disc space through sheath as described on p. 63

after multiple corrugated cages are deployed within each other the shape-memory corrugations of each hollow cylinder expands - the combined force separates the endplates. The cylinder serrated edges "dig into" the exposed cancellous bone and secure the cages in place. Collections of these "coaxial" cages are placed bilaterally within the disc space through a bipedicular approach. The central space within these constructs is filled c̄ bone matrix material + BMP to encourage bony union between the endplates

Teflon-coated ~~flat~~ concave nitinol wire formed into a tight spiral which can act as a dilatation device and a supportive structure in spinal fusion. Potentially could be used in endplate elevation in the case of spinal compression fractures (i.e., the kyphoplasty procedure):

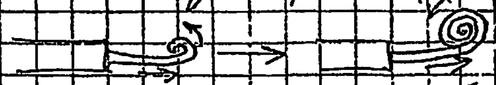


Cross-section:



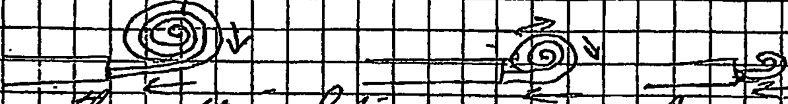
Nitinol is heat-annealed into spiral shape.

When "spiral dilator" is first pushed from its delivery catheter (may also be hammered), it begins forming tight turns of spiral.



As the growing wire disc enlarges, its surfaces come into contact with the surfaces to be dilated. Teflon coating assists the disc in rotating against these surfaces.

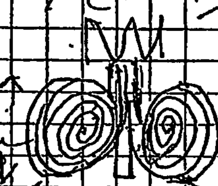
when one is through dilating with this device, the spiral is merely pulled out through its delivery catheter – the spiral shape "unwinds" as it ~~is~~ is removed:



Or, the spiral disc may be left in the patient as a structural element.

One design for a disc space "spreading" device might be:

← anchoring, self-expanding stent (or some other anchoring mechanism)



1cm

2cm

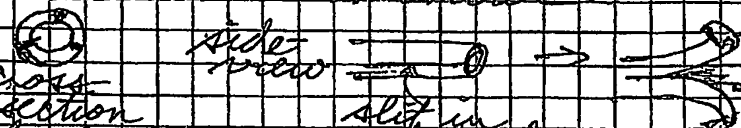
3 spiral nitinol wire discs make up device

Bottom view:

2cm

disc width = approx 3.5mm each

This "tri-coil" design could be manufactured ~~by~~ from a single nitinol tube ~3.5mm in diameter.



Cross section

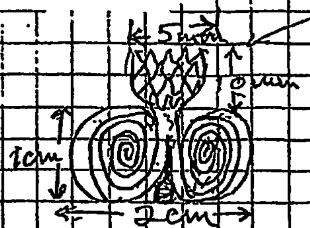
Side view

slit in metal tube

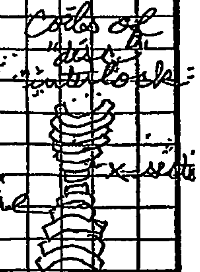
By grinding, the tube thickness is lessened distally to increase flexibility

Central lumen of nitinol tube may allow insertion of a small nail or screw to aid in securing device to lower endplate

and ease insertion and removal of device.

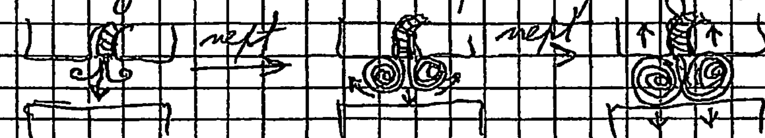


Proximal anchoring self-expanding segment could be composed of multiple interconnected laser-cut zig-zag (wvv) rings derived from the same nitinol tube as the spiral discs.



The device is inserted using the same techniques described on page 63:

Side View:

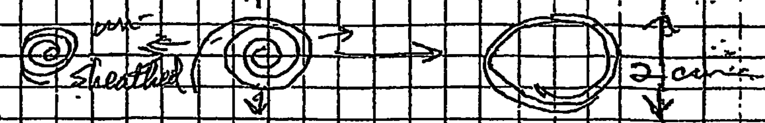


Either the device could be inserted bilaterally as merely a disc space height increaser (and removed before some other "cage"-like device is inserted) or it could be left in place, secured with the proximal "stent" segment + possibly a central nail or screw to secure the device to the lower endplate. Left in place the tri-coil device would be a supportive element in an interbody fusion. In this case, the tri-coil device would be enveloped c̄ bone matrix material + BMP after insertion. The bone matrix (e.g. Vitoss flow Orthovita) could be contained within a self-expanding metal sleeve that would be inserted into the disc space before the ~~tri~~ tri-coil device, again using techniques described on page 63.

Matrix Sleeve device:

Top view:

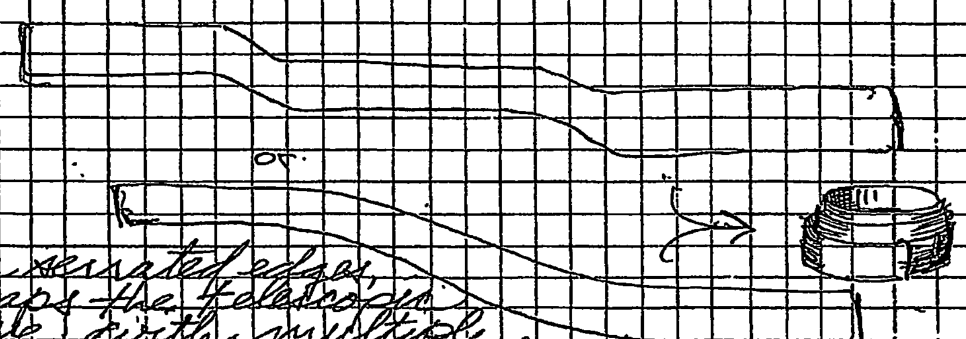
Delivered wound-up like a watch spring



Side view:

"Telescoping" design allows sleeve to spring open in narrower disc spaces and then increase in height as the spinal dilator increases the height of the disc space.

Construction of telescoping self-expanding sleeve:



With serrated edges, perhaps the telescoping sleeve with multiple "sleeves" or layers deployed within one another could independently act as a fusion device if multiple sleeves could collectively generate enough lifting force to raise the disc space height and support bony fusion without the need for a spinal dilator.

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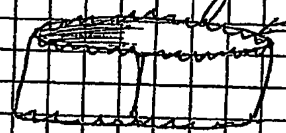
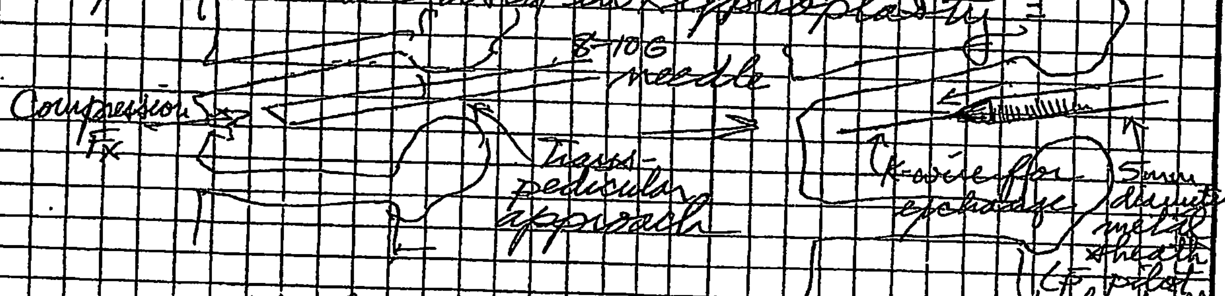
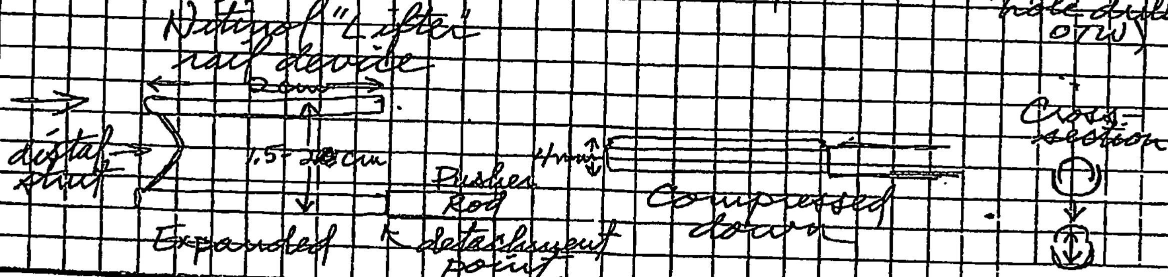
Alternatively, c̄ a retrievable spiral dilator, once there has been sufficient disc space widening, the tri-coil (or perhaps it could merely be a unicoil device) would be removed and then a simple "watch-spring" expandable metal sleeve (similar to the device depicted on p. 64, except without the corrugations or the ability to increase its height) could be deployed in multiple layers until sufficient collective strength is achieved to support the spinal axial compressive forces.

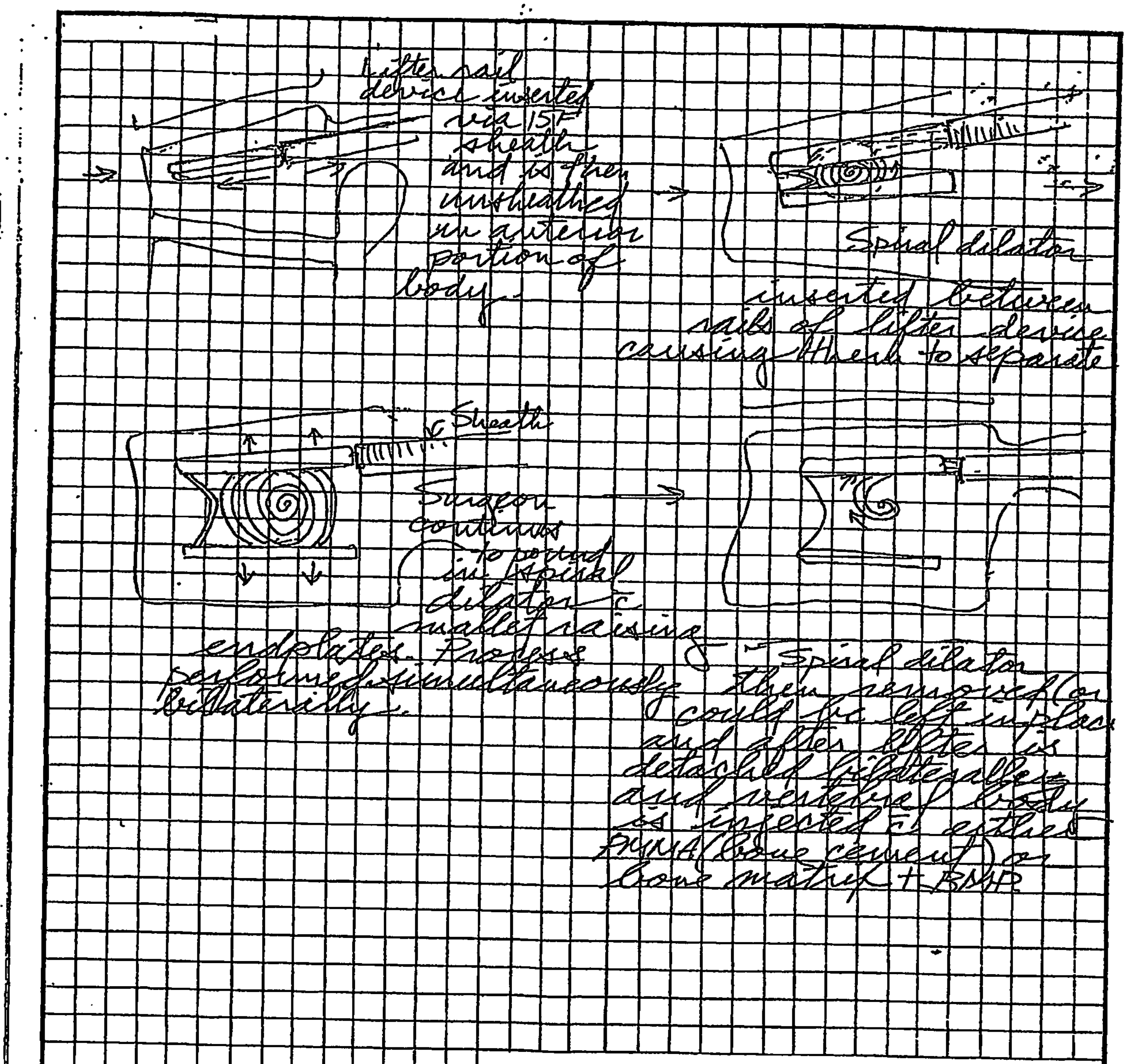


= Spiral dilator used in kyphoplasty =

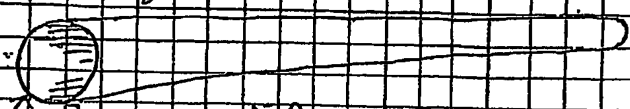




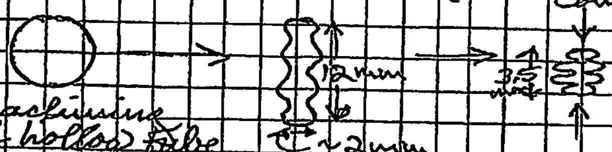
60[illegible]4948 - 110802



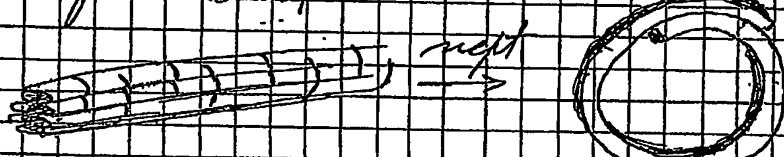
Constructed from 10mm wide Nitinol tube =



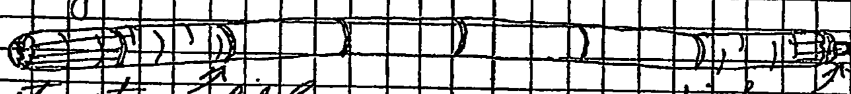
~0.25mm thick wall



To make construct more flexible for transcatheter delivery [illegible] cuts are made along length of construct:



Entire construct enveloped c̄ high-density nylon or polyester jacket c̄ hydrophilic coating:



(Construct could be kept constrained during delivery by thin strong polyethylene bands that break open)

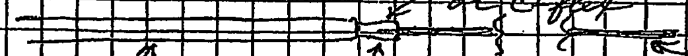
high-pressure self-sealing valve at proximal end

Delivery catheter for construct:

slotted silicone or C-flex

H_2O or

inner saline delivery catheter

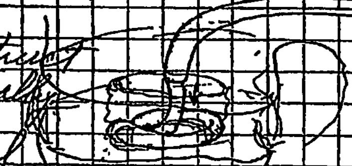


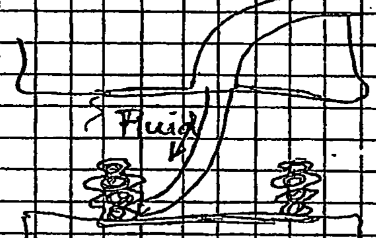
Braided 10F outer catheter (pusher)

Locking mechanism that slips over ~~as~~ self-sealing valve. Outer catheter slips over locking device allowing construct to be Retrieved, if necessary.

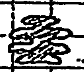
Bilaterally, after establishment of trans-osseous pathway, and placement of delivery sheath (≈ 3.5-3.65 mm ID), construct is loaded on pusher/delivery catheter and advanced via trans-pedicular pathway into already prepared disc space.

The construct automatically forms a spiral once extruded ~~fr~~ from the delivery catheter.

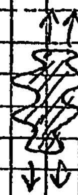




The constructs are inserted with H_2O or saline under pressure



The hydrogel absorbs fluid and expands to many times its original volume



The force of hydrogel expansion + the nitinol's shape memory work to raise the height of the cylinder walls

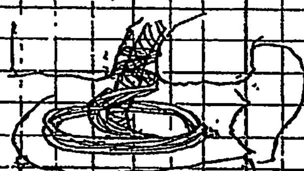
Expansile force raises disc space height

Construct detached in disc space

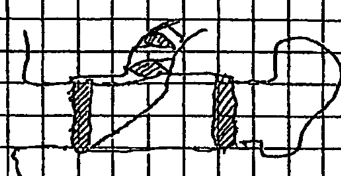
A second or third layer of expanding nitinol "spiral" cylinders can be placed within one another to increase overall construct strength.

Space now filled c bone matrix + BMP

The inner most cylinder could have a proximal helical nitinol tail that would deploy back into the transosseous pathway thus securing the overall construct into the disc space.



Construct expanded and detached



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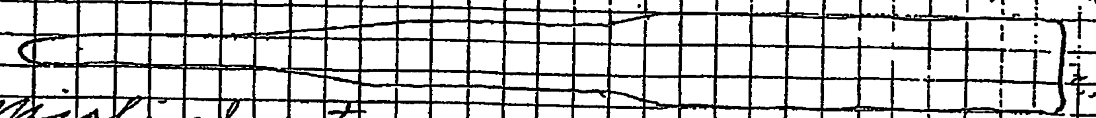
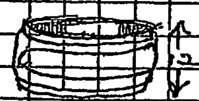
long, thin nitinol band:

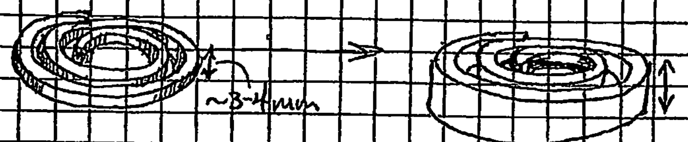


Machined into
hollow ~~shape~~ cylinder
composed of of a spiral configuration
of the above band:



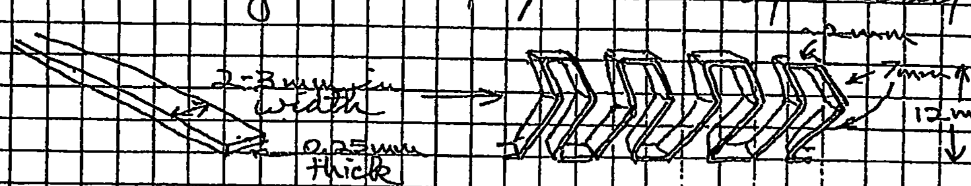
The construct could
be deployed either
wound up like a
watch spring or
stretched out in a long catheter.
As the widening width of each
progressive spiral is deployed, it
acts as a gradual dilator, progressive
increasing the disc space height.

General idea is to insert a spiral internal construct that will increase in height with sufficient force to increase the disc space height.

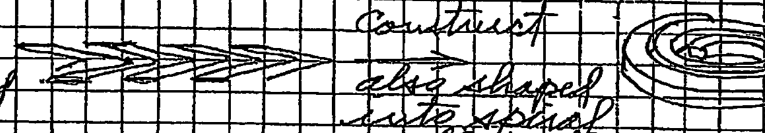


Once deployed in disc space construct expands spirally

The constructs would be fabricated from a single band of nitinol metal.



Construct compressed down



Construct also shaped into spiral configuration

Construct kept contained in compressed form by thin polyether (or other suitable plastic) envelop.

thermal release system creates tear in envelop "unzipping" it

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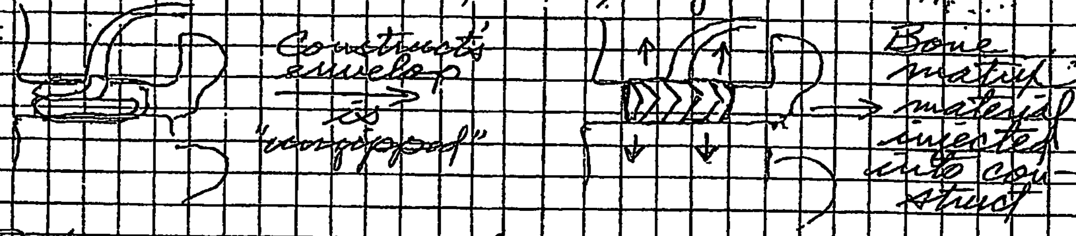
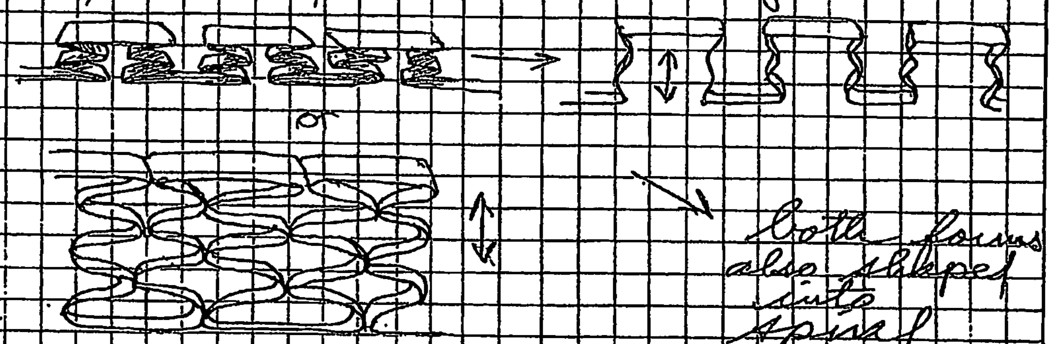
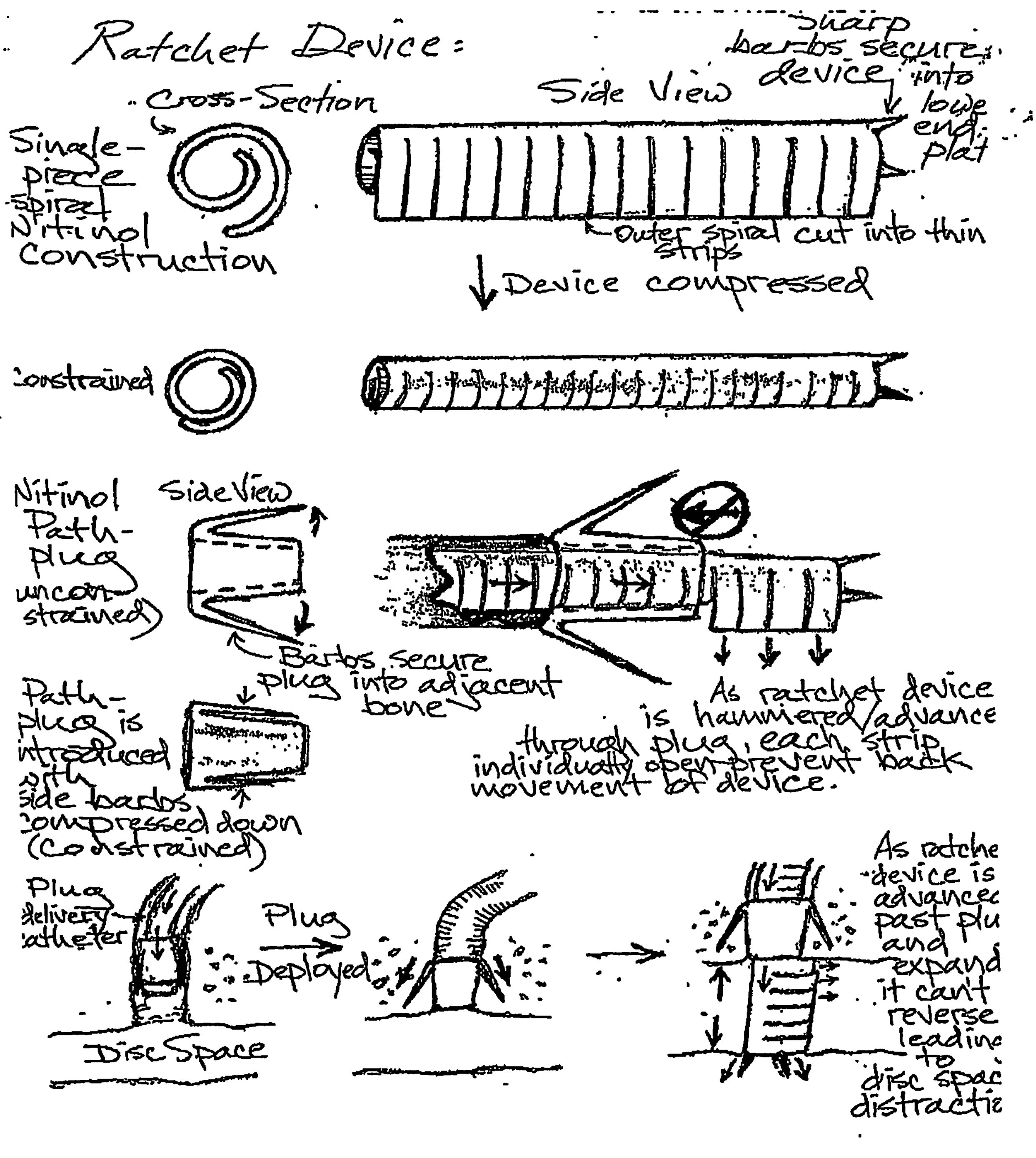
Construct introduced into prepared disc space as described on pages 63, 68 & 78

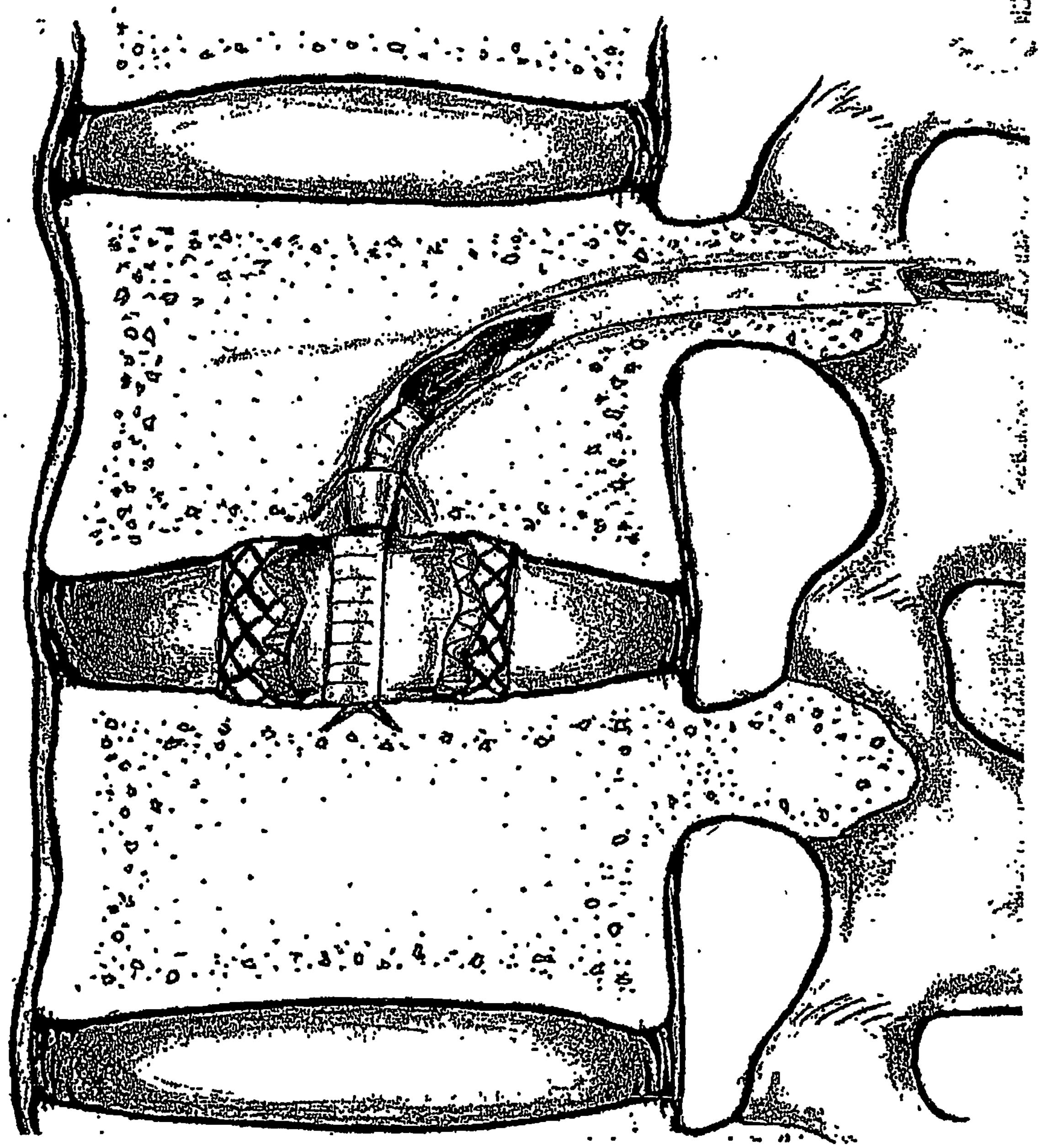


Outer ring of spiral construct would have to have a thin, flexible plastic or silastic layer to help contain the damp bone matrix material.

Other potential construct designs:




Ratchet Device:
Cross-Section
Single-piece spiral Nitinol Construction
Side View
Sharp barbs secure device into lowe end plat
Outer spiral cut into thin strips
Device compressed
constrained
Nitinol Path-plug unconstrained
SideView
Barbs secure plug into adjacent bone
Path-plug is introduced with side barbs compressed down (constrained)
As ratchet device is hammered/advance through plug, each strip individually open prevent back movement of device.
Plug delivery catheter
Plug Deployed
Disc Space
As ratche device is advanced past plu and expand it can't reverse leading to disc spac distractio



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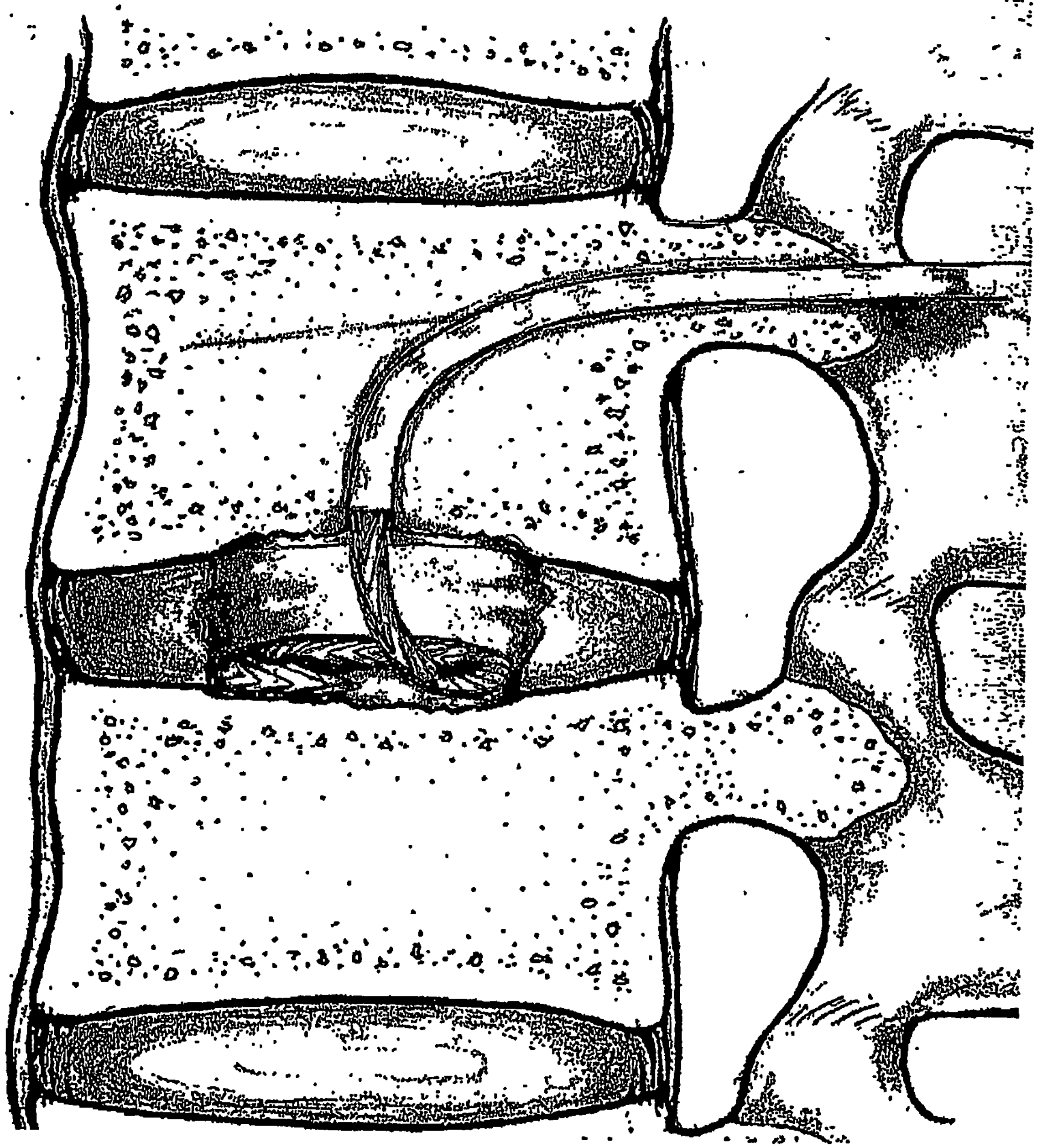

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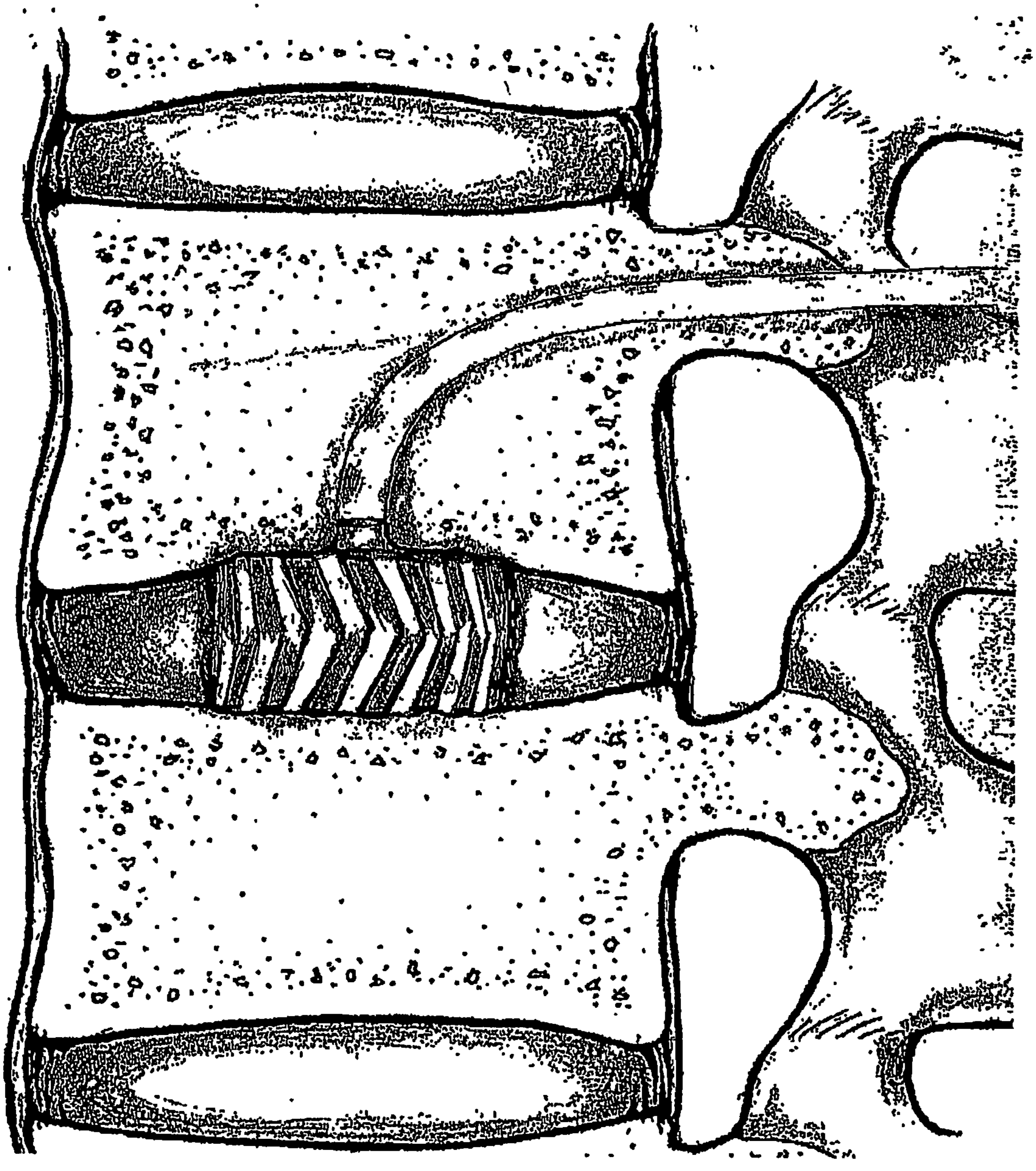
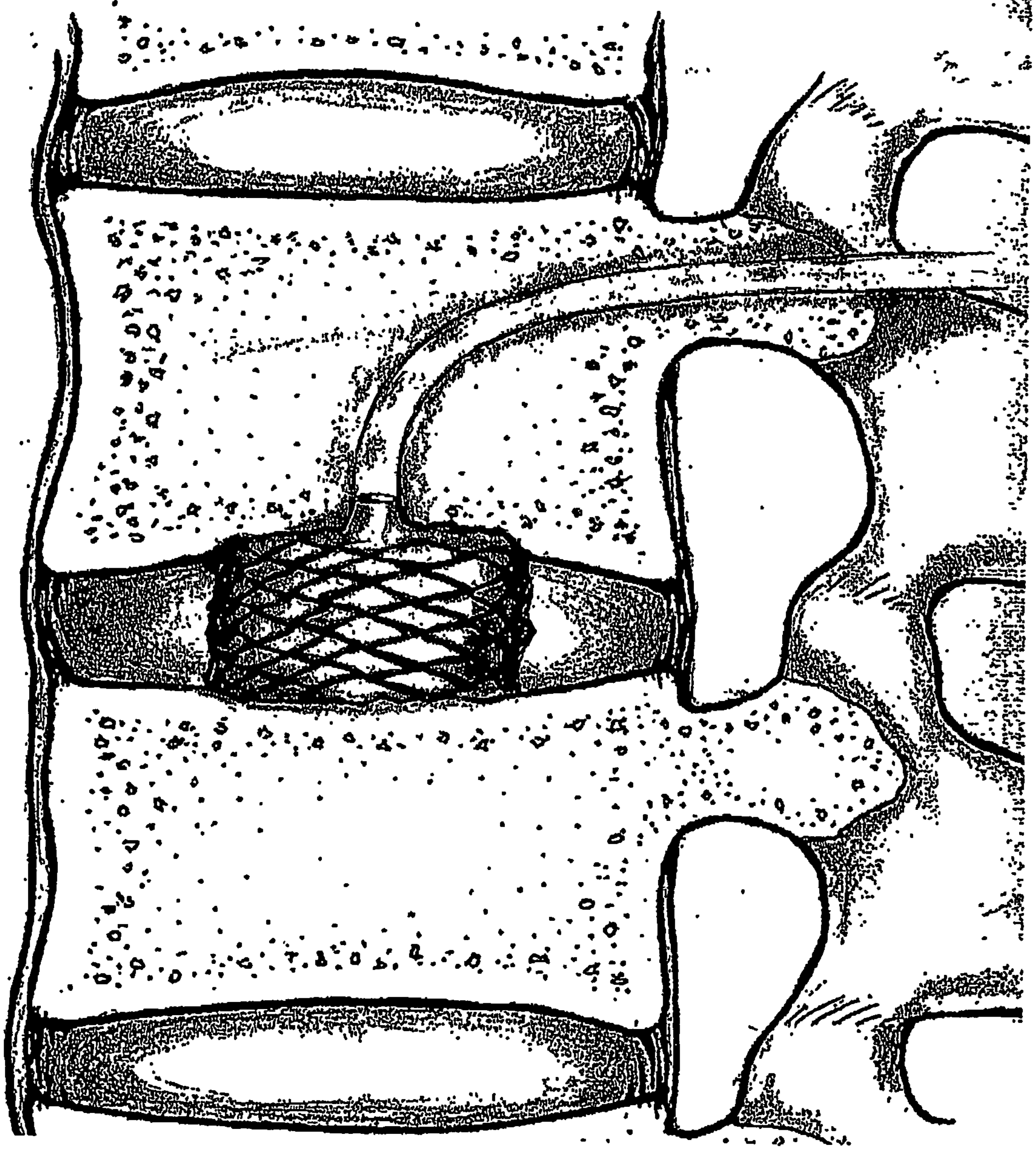
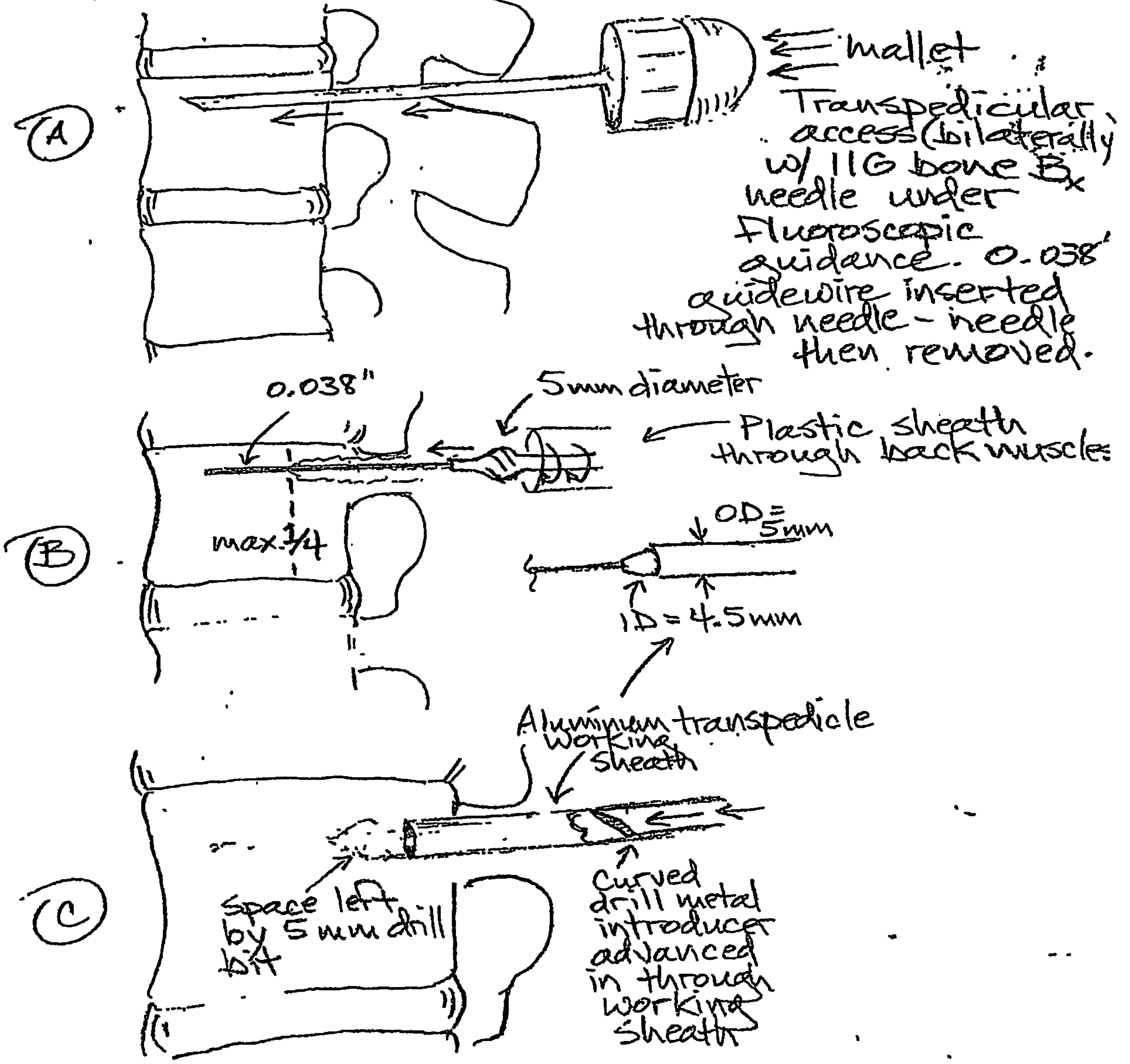
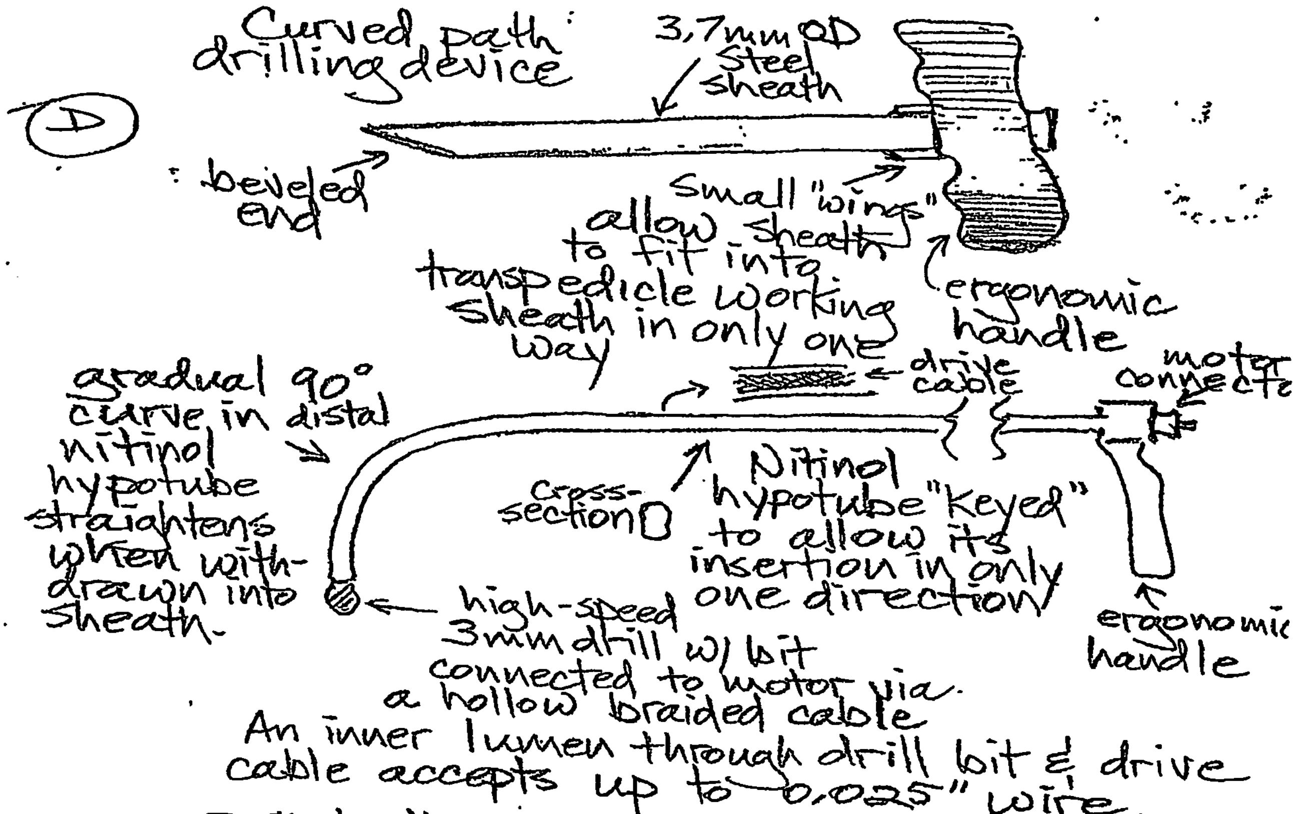
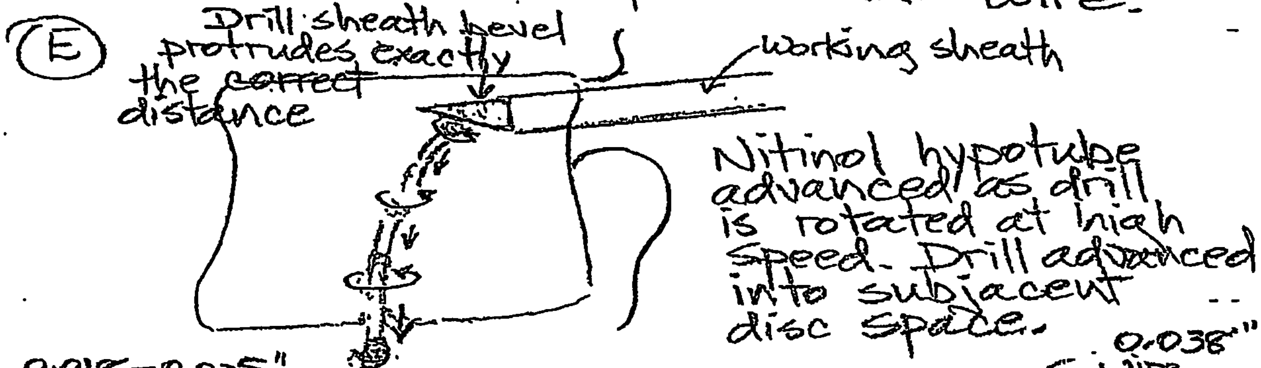


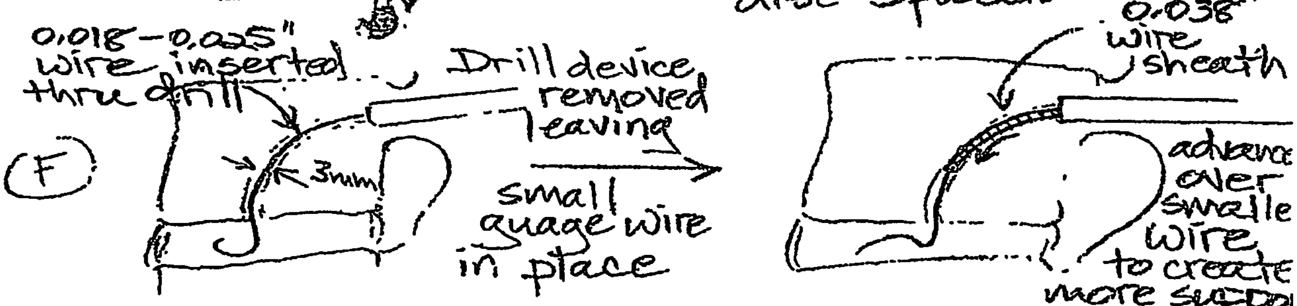


Spine Fusion Procedure

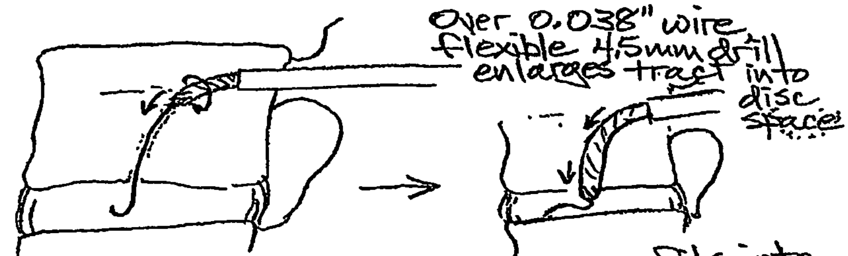


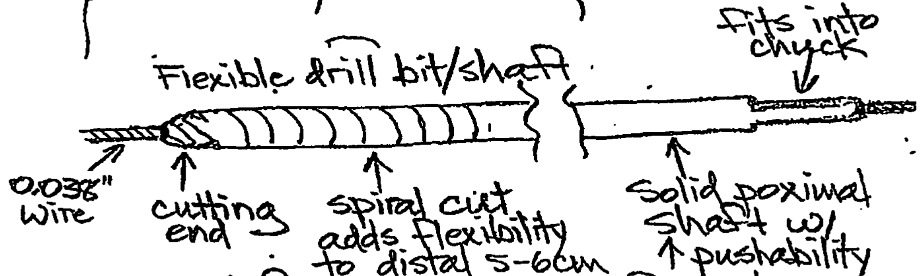

Curved path drilling device
(D)
3,7mm OD Steel sheath
beveled end
Small "wings" allow sheath to fit into transpedicle working sheath in only one way
ergonomic handle
gradual 90° curve in distal nitinol hypotube straightens when with-drawn into sheath.
drive cable
motor connecte
Cross-section
Nitinol hypotube "keyed" to allow its insertion in only one direction
high-speed 3mm drill w/ bit connected to motor via a hollow braided cable
ergonomic handle
An inner lumen through drill bit & drive cable accepts up to 0,025" wire.


(E)
Drill sheath bevel protrudes exactly the ~~correct~~ distance
working sheath
Nitinol hypotube advanced as drill is rotated at high speed. Drill advanced into subjacent disc space.


0,018–0,025" wire inserted thru drill
(F)
3mm
Drill device removed leaving small guage wire in place
0,038" wire sheath
advance over smalle wire to create more suppo

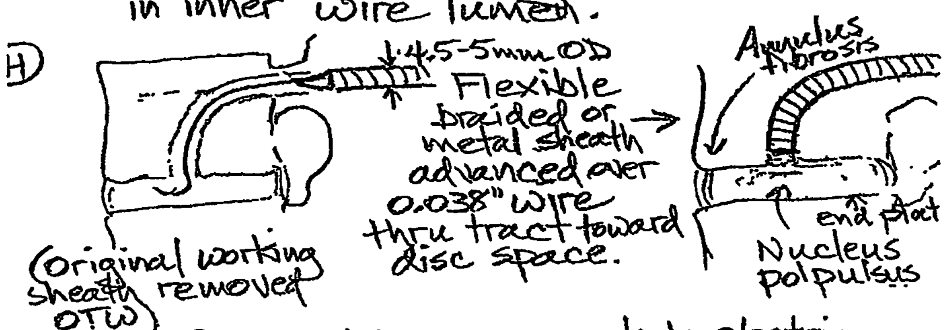
3)



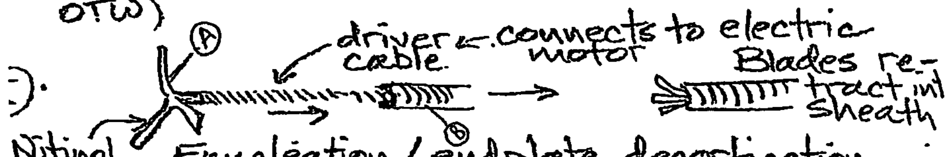


Outer teflon coating + teflon sleeve
in inner wire lumen.

4)



5).



Enucleation/endplate decortication
device. Removes disc material and
exposes cancellous bone prior to
interbody fusion.

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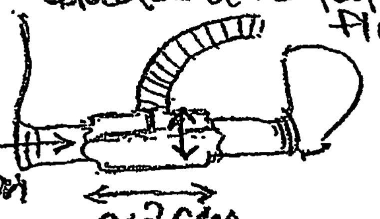
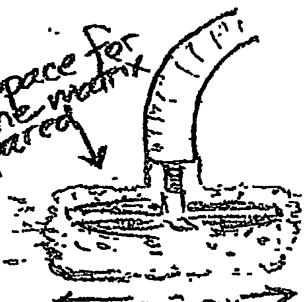
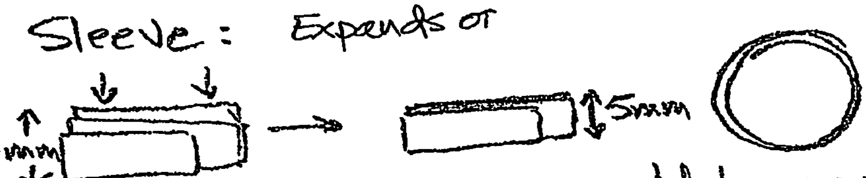
(J) Expanded, spinning blades directed by fluoro





Afterwords, debris flushed out of disc space w/ saline.

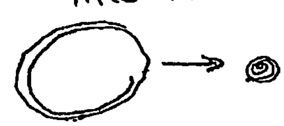
(K) Sleeve: Expands or

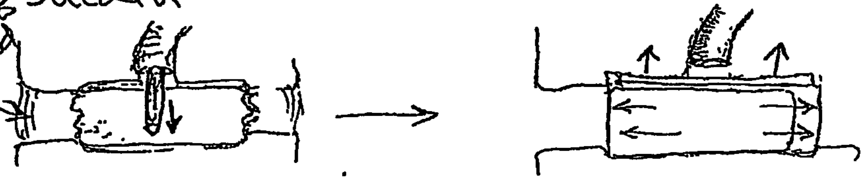


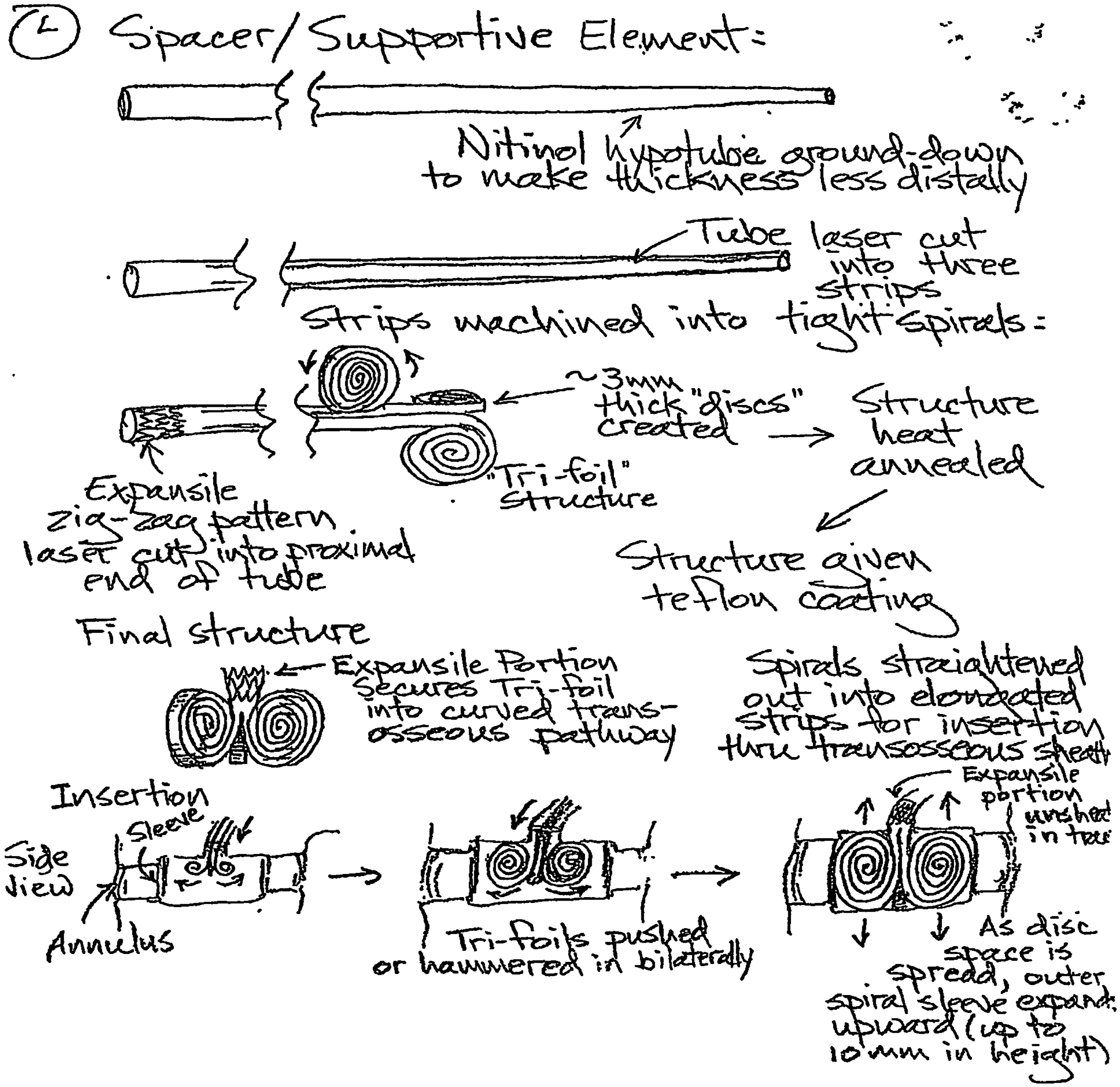
Thin nitinol spiral band - could be coated with thin layer of hydrogel to cause tight seal after deployment. Sleeve acts to hold in mass of putty-like bone matrix (e.g., Vitoss from Orthovita mixed w/ BMP + bone marrow).

Deployment Device:

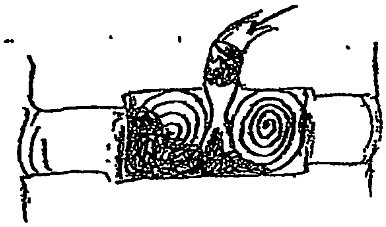
Sleeve wound-up like watch spring:



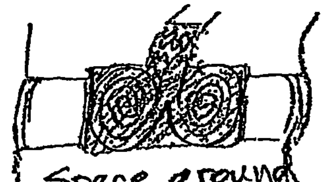



(2) Spacer/Supportive Element:
Nitinol hypotube ground-down to make thickness less distally
Tube laser cut into three strips
Strips machined into tight spirals:
~3mm thick "discs" created
Structure heat annealed
"Tri-foil" structure
Expansile zig-zag pattern laser cut into proximal end of tube
Structure given teflon coating
Final structure
Expansile Portion secures Tri-foil into curved trans-osseous pathway
Spirals straightened out into elongated strips for insertion thru transosseous sheath
Insertion
Sleeve
Side View
Annulus
Tri-foils pushed or hammered in bilaterally
Expansile portion unsheathed in track
As disc space is spread, outer spiral sleeve expands upward (up to 10mm in height)

(M) Injection of Bone Matrix Material

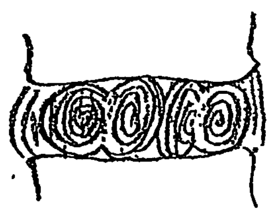


→

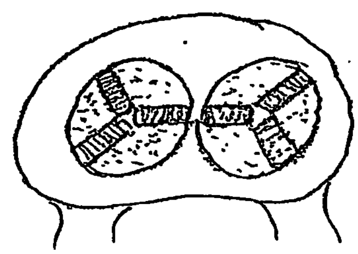


Space around trifoils completely filled c̄ bone matrix

Front View:



Top View:



Procedure now completed with placement of pedicle screws and rods through same tissue/transpedicular tracts.

WHAT IS CLAIMED IS:

1. A method for treating diseases and conditions that change the spacial relationship between the vertebral bodies and the intervertebral discs, or that cause instability of the vertebral column, or both, and a method that allows the surgeon to directly access the intervertebral space to directly restore a more normal three-dimensional configuration of the space, with or without additionally fusing two adjacent vertebrae as disclosed in this disclosure.

2. A curved bone drill as disclosed in this disclosure.

3. An enucleation device as disclosed in this disclosure.

FIGURE 20

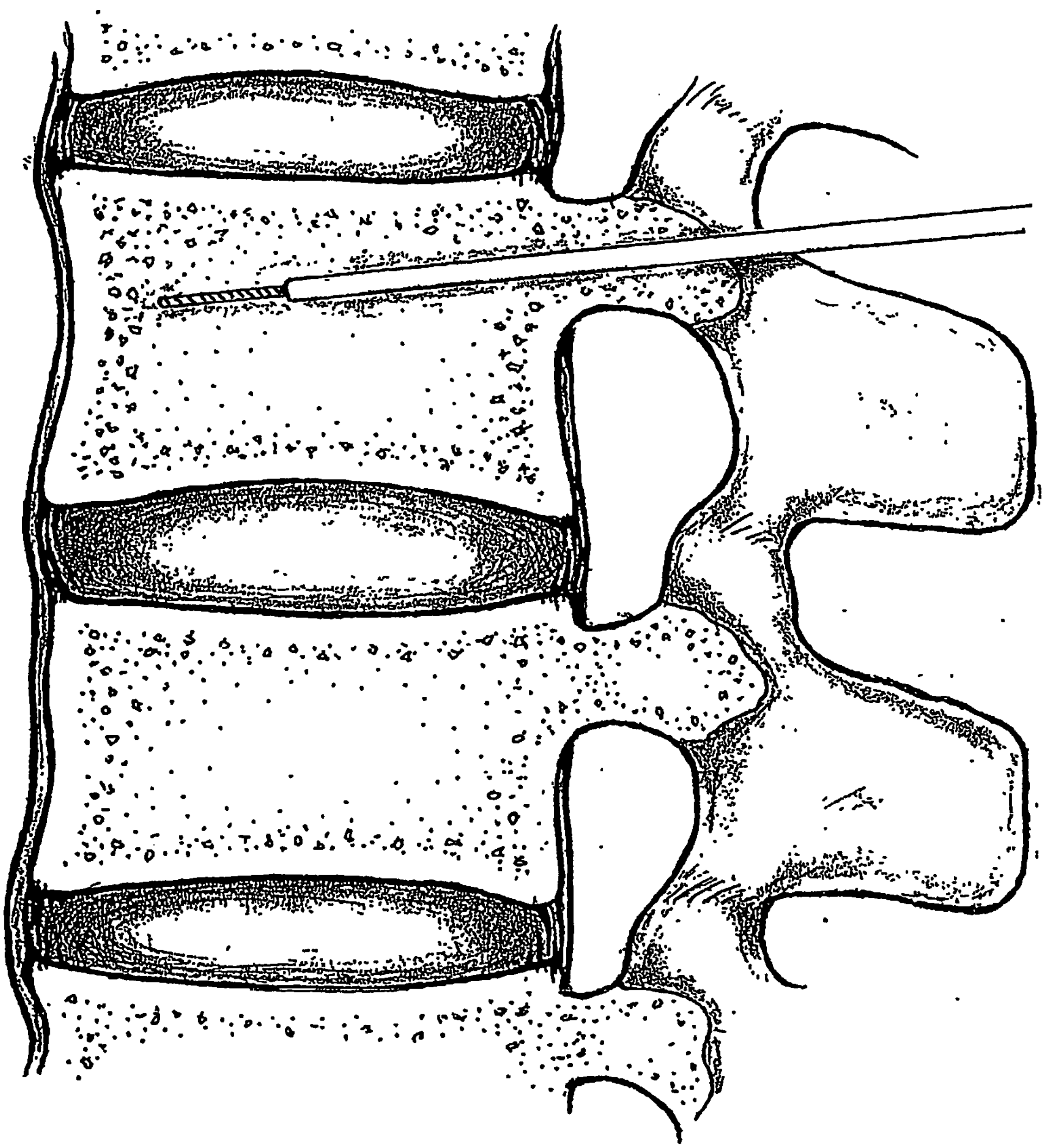
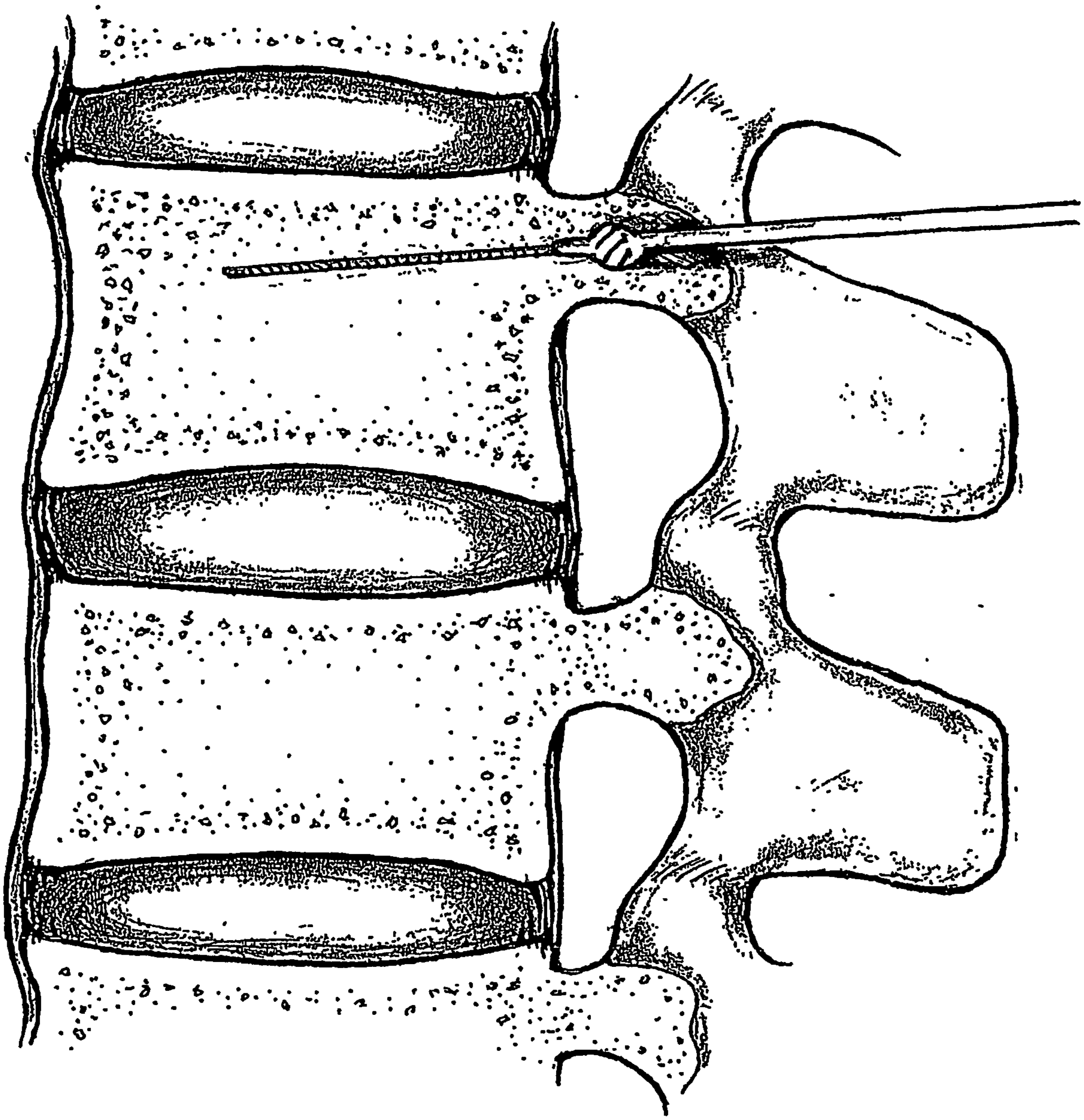


FIGURE 21



60[illegible]442.110802

FIGURE 22

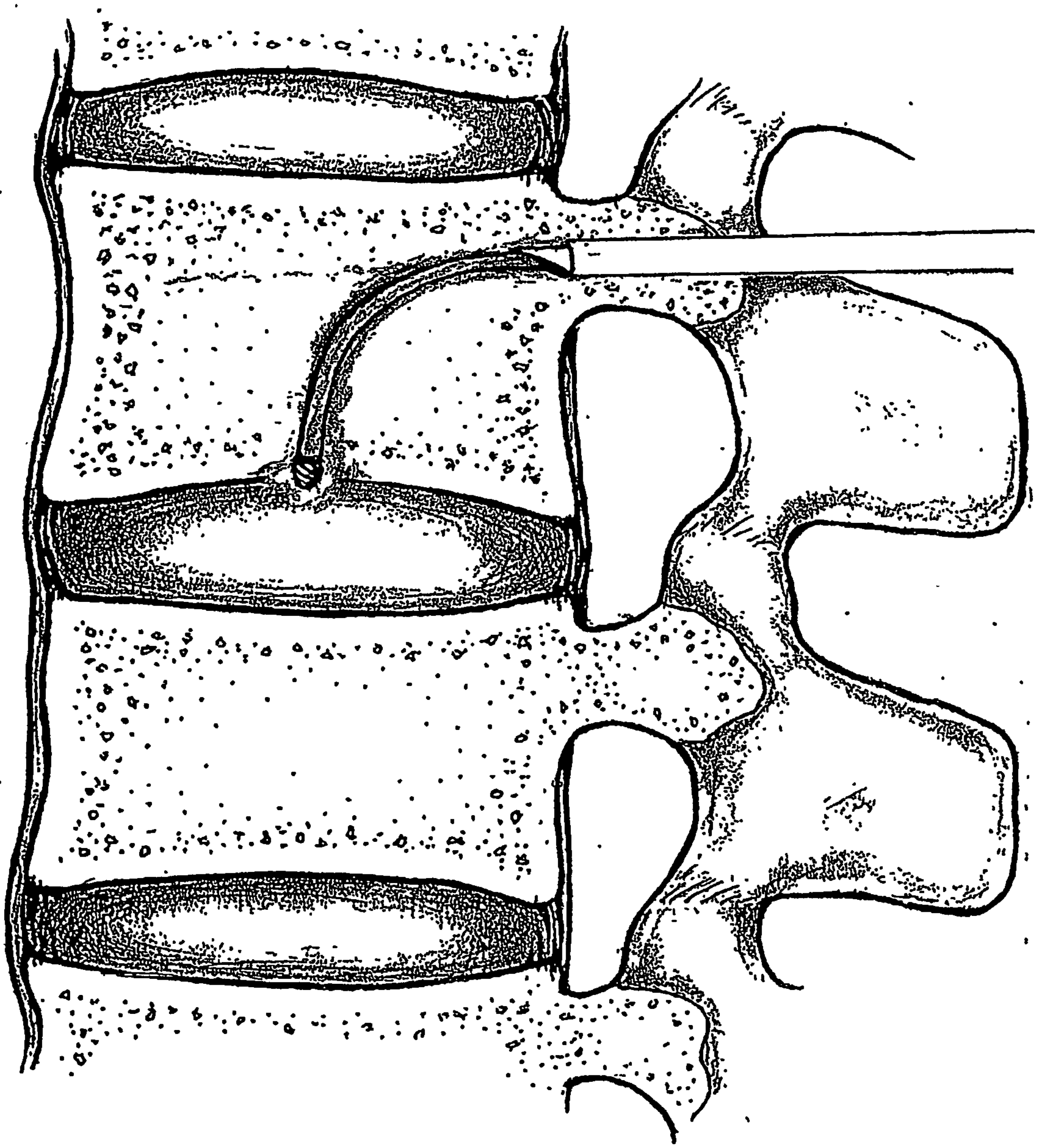


FIGURE 23

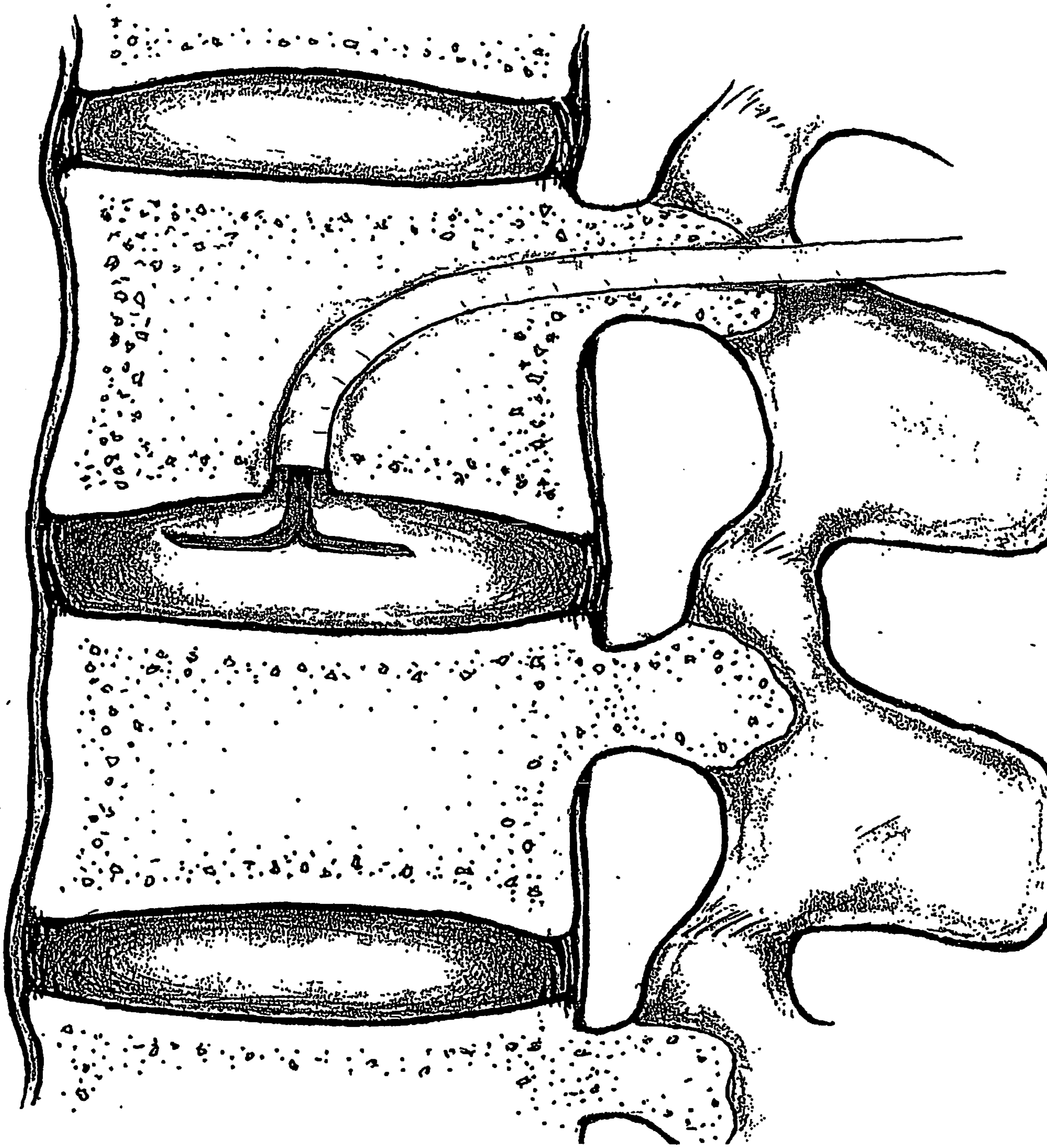


FIGURE 24

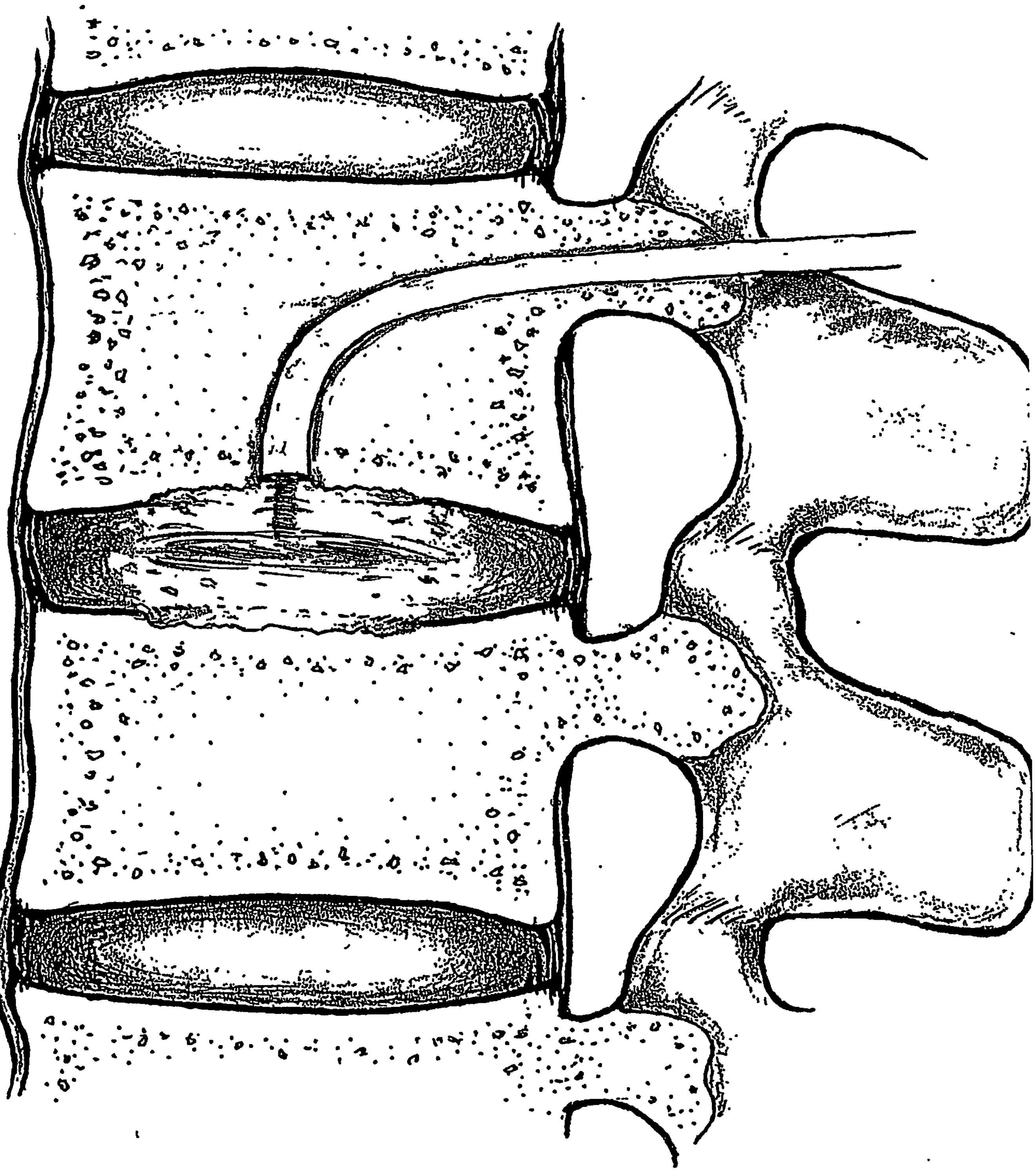


FIGURE 25

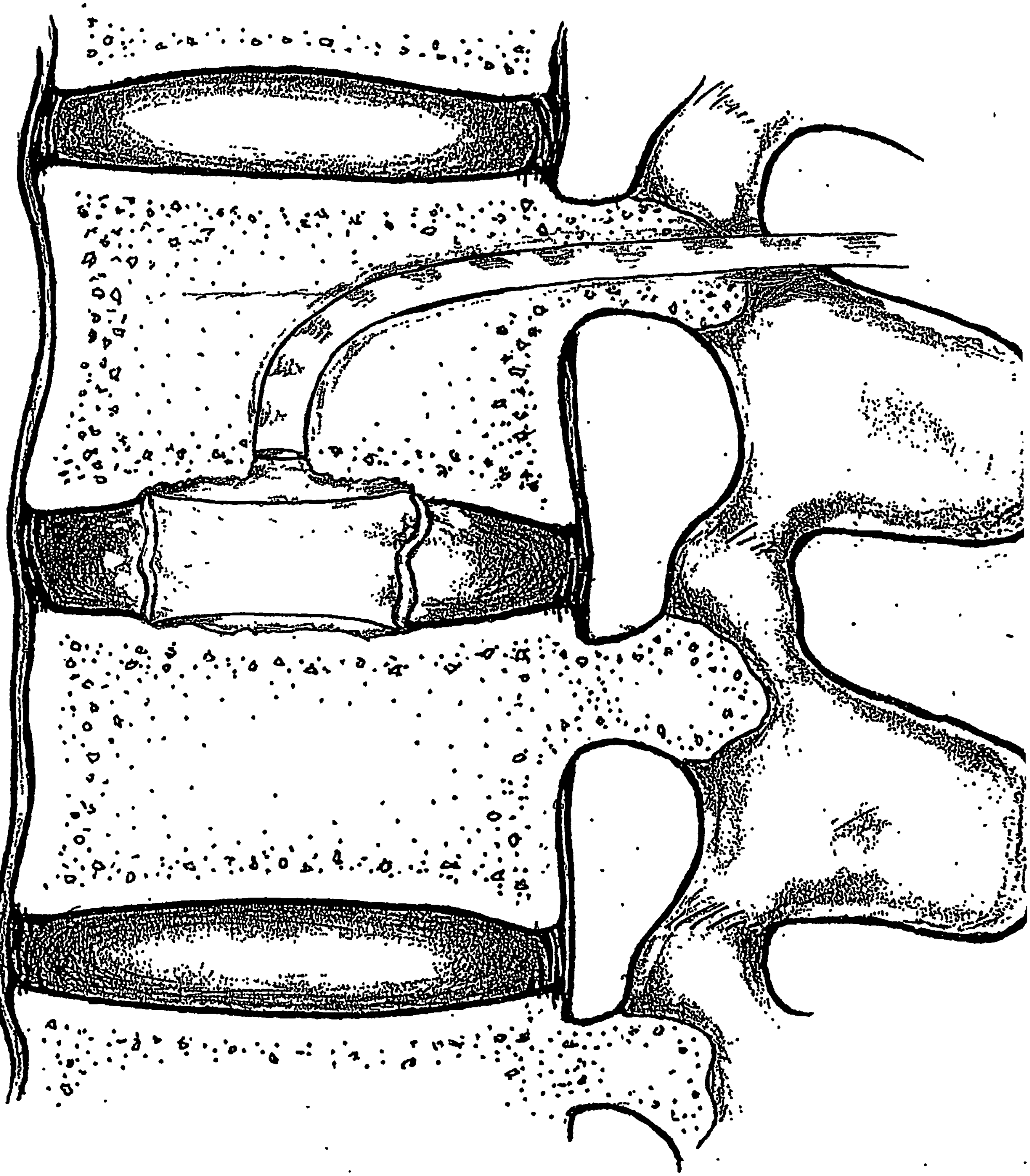


FIGURE 26

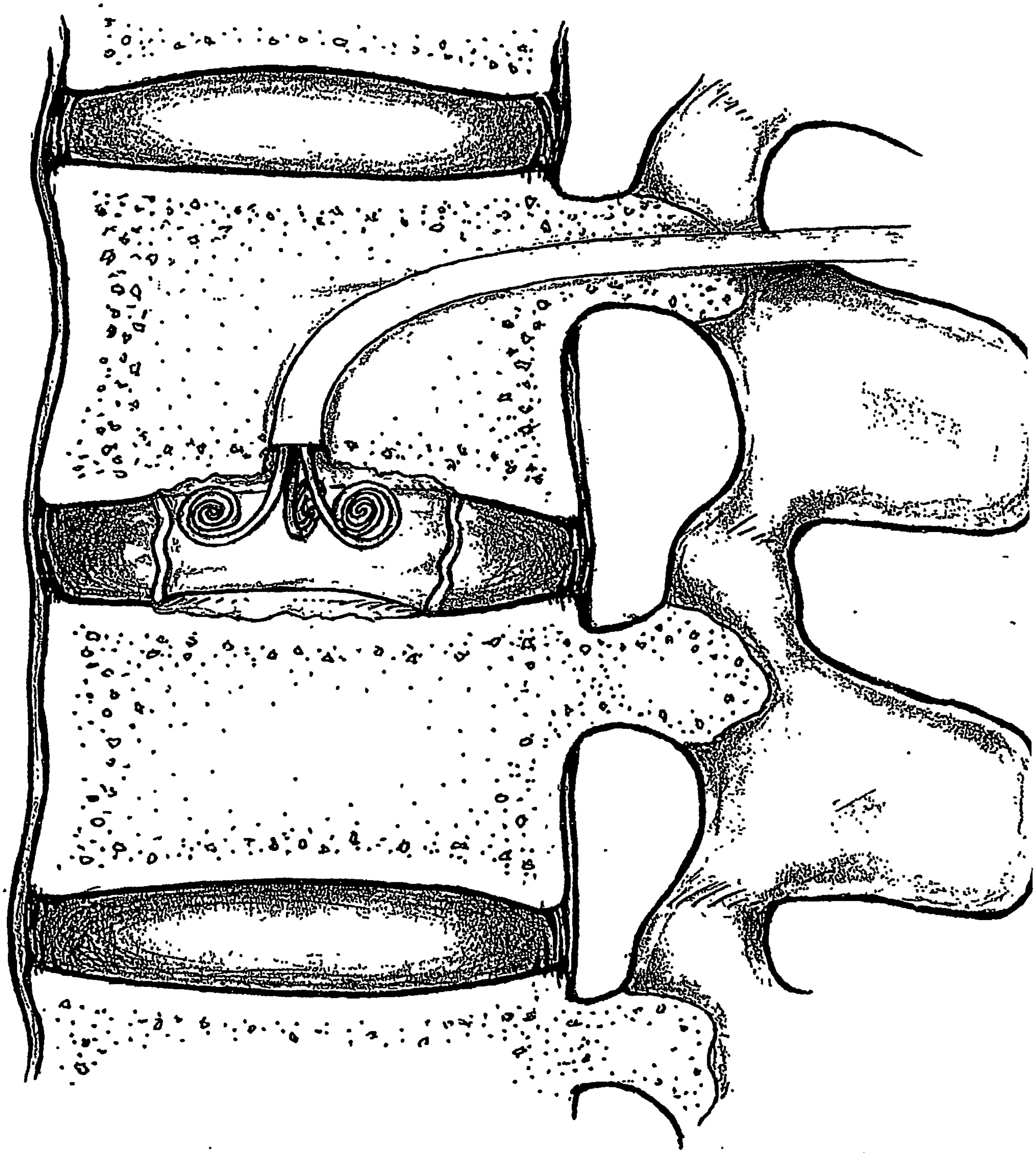


FIGURE 27

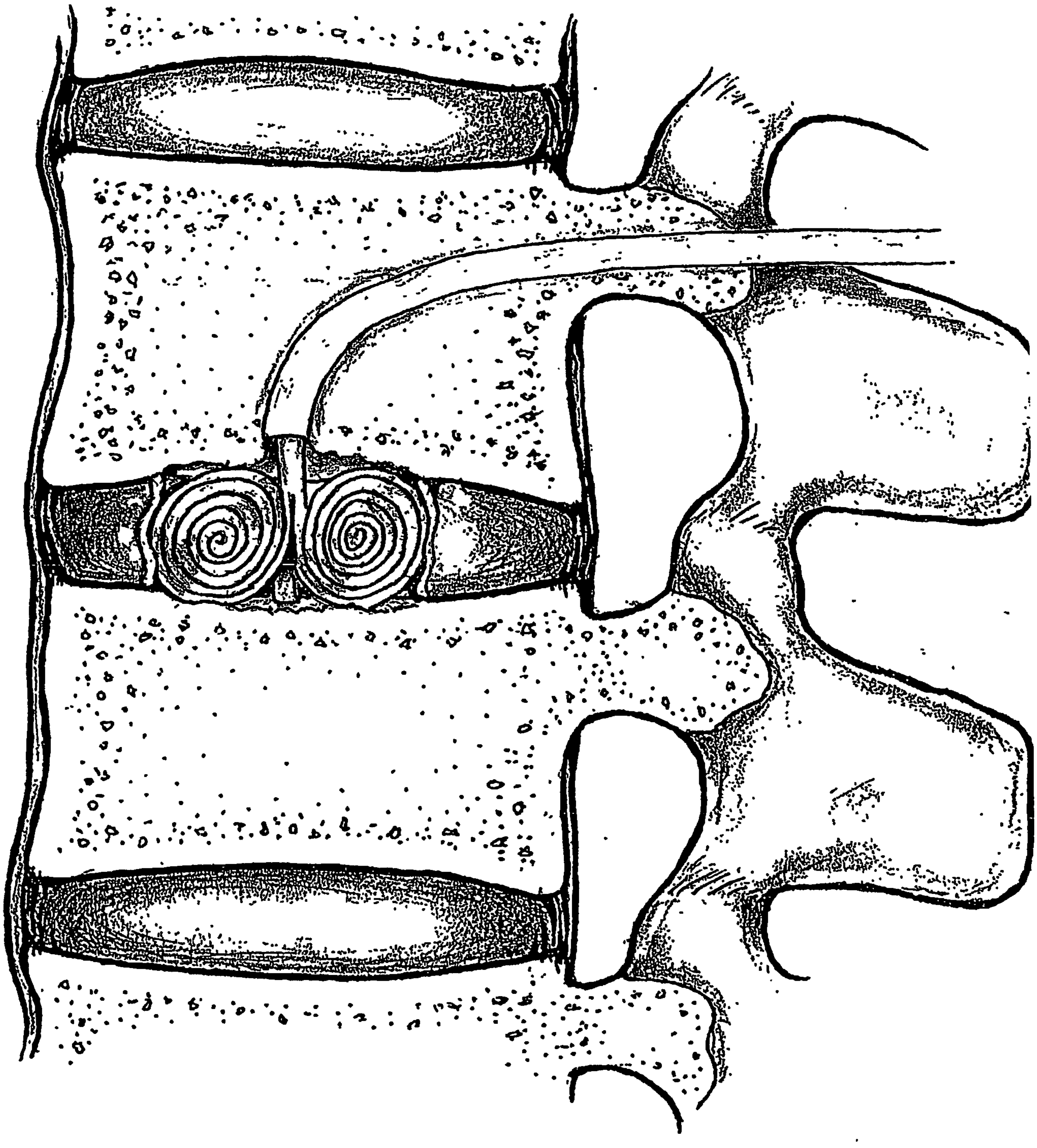


FIGURE 28